



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<b>(51) International Patent Classification <sup>6</sup>:</b>  <b>A61H</b>	<b>A2</b>	<b>(11) International Publication Number:</b> <b>WO 99/63926</b>  <b>(43) International Publication Date:</b> 16 December 1999 (16.12.99)
<b>(21) International Application Number:</b> PCT/US99/13161  <b>(22) International Filing Date:</b> 10 June 1999 (10.06.99)  <b>(30) Priority Data:</b> 09/095,916 11 June 1998 (11.06.98) US 09/197,286 20 November 1998 (20.11.98) US 09/315,396 20 May 1999 (20.05.99) US  <b>(71) Applicant:</b> CPRx, LLP [US/US]; 4751 Girard Avenue South, Minneapolis, MN 55409 (US).  <b>(72) Inventors:</b> LURIE, Keith, G.; 4751 Girard Avenue South, Minneapolis, MN 55409 (US). BENDITT, David, G.; #2 Circle West, Edina, MN 55436 (US). ZIELINSKI, Todd, M.; 48 27th Avenue S.E. #203, Minneapolis, MN 55414 (US). VOECKEL, Wolfgang; Krehbachgasse 13C, A-6410 Telfs (AT). PATTERSON, Robert; 3761 Foss Road, Minneapolis, MN 55421 (US).  <b>(74) Agents:</b> GIBBY, Darin, J. et al.; Townsend and Townsend and Crew LLP, 8th floor, Two Embarcadero Center, San Francisco, CA 94111 (US).		<b>(81) Designated States:</b> AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).  <b>Published</b> <i>Without international search report and to be republished upon receipt of that report.</i>
<b>(54) Title:</b> STIMULATORY DEVICE AND METHODS TO ENHANCE VENOUS BLOOD RETURN DURING CARDIOPULMONARY RESUSCITATION  <b>(57) Abstract</b>  The invention provides exemplary devices and methods for increasing cardiopulmonary circulation when performing cardiopulmonary resuscitation. In one exemplary method, a patient's chest is actively compressed during a compression phase. At least some of the respiratory muscles are stimulated to contract during a decompression phase to cause an increase in the magnitude and duration of negative intrathoracic pressure during the decompression phase. In this way, the amount of venous blood flow into the heart and lungs is enhanced.		

Best Available Copy

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

## STIMULATORY DEVICE AND METHODS TO ENHANCE VENOUS BLOOD RETURN DURING CARDIOPULMONARY RESUSCITATION

### 5 CROSS-REFERENCES TO RELATED APPLICATIONS

This application is a continuation in part application of U.S. Patent Application Serial No. 09/197,286, filed November 20, 1998, which is a continuation in part application of U.S. Patent Application Serial No. 09/095,916, filed June 11, 1998, the complete disclosures of which are herein incorporated by reference.

10

### BACKGROUND OF THE INVENTION

The invention relates generally to the field of cardiopulmonary resuscitation and artificial ventilation. In particular, the present invention relates to devices and methods for increasing cardiopulmonary circulation during cardiopulmonary resuscitation procedures involving.

15 Worldwide, sudden cardiac arrest is a major cause of death and is the result of a variety of circumstances, including heart disease and significant trauma. In the event of a cardiac arrest, several measures have been deemed to be essential in order to improve a patient's chance of survival. These measures must be taken as soon as possible to at least partially restore the patient's respiration and blood circulation. One common technique, developed approximately 30 years ago, is an external chest compression technique generally referred to as cardiopulmonary resuscitation (CPR). CPR techniques have remained largely unchanged over the past two decades. With traditional CPR, pressure is applied to a patient's chest to increase intrathoracic pressure. An increase in

20 intrathoracic pressure induces blood movement from the region of the heart and lungs towards the peripheral arteries. Such pressure partially restores the patient's circulation.

25 Traditional CPR is performed by active compressing the chest by direct application of an external pressure to the chest. This phase of CPR is typically referred to as the compression phase. After active compression, the chest is allowed to expand by its natural elasticity which causes expansion of the patient's chest wall. This phase is often referred to as the relaxation or decompression phase. Such expansion of the chest allows some blood to enter the cardiac chambers of the heart. The procedure as described, however, is insufficient to ventilate the patient. Consequently, conventional CPR also

30

requires periodic ventilation of the patient. This is commonly accomplished by a mouth-to-mouth technique or by using positive pressure devices, such as a self-inflating bag which delivers air through a mask, an endotracheal tube, or other artificial airway.

In order to increase cardiopulmonary circulation induced by chest  
5 compression, a technique referred to as active compression-decompression (ACD) has been developed. According to ACD techniques, the active compression phase of traditional CPR is enhanced by pressing an applicator body against the patient's chest to compress the chest. Such an applicator body is able to distribute an applied force substantially evenly over a portion of the patient's chest. More importantly, however, the  
10 applicator body is sealed against the patient's chest so that it may be lifted to actively expand the patient's chest during the relaxation or decompression phase. The resultant negative intrathoracic pressure induces venous blood to flow into the heart and lungs from the peripheral venous vasculature of the patient. Devices and methods for performing ACD to the patient are described in U.S. Patent Nos. 5,454,779 and  
15 5,645,552, the complete disclosures of which are herein incorporated by reference.

Another successful technique for increasing cardiopulmonary circulation is by impeding air flow into a patient's lungs during the relaxation or decompression phase. By impeding the air flow during the relaxation or decompression phase, the magnitude and duration of negative intrathoracic pressure is increased. In this way, the amount of  
20 venous blood flow into the heart and lungs is increased. As a result, cardiopulmonary circulation is increased. Devices and methods for impeding or occluding the patient's airway during the relaxation or decompression phase are described in U.S. Patent Nos. 5,551,420 and 5,692,498 and co-pending U.S. Application Serial No. 08/950,702, filed October 15, 1997. The complete disclosures of all these references are herein  
25 incorporated by reference.

The above techniques have proven to be extremely useful in enhancing traditional CPR procedures. As such, it would be desirable to provide still further techniques to enhance venous blood flow into the heart and lungs of a patient from the peripheral venous vasculature during both conventional and alternative CPR techniques.  
30 It would be particularly desirable to provide techniques which would enhance oxygenation and increase the total blood return to the chest during the relaxation or decompression phase of CPR.

## SUMMARY OF THE INVENTION

The invention provides methods and devices for increasing cardiopulmonary circulation when performing cardiopulmonary resuscitation. The methods and devices may be used in connection with most generally accepted CPR methods. In one exemplary method, a patient's chest is actively compressed during the compression phase of CPR. At least some of the respiratory muscles, and particularly the inspiratory muscles, are then stimulated to contract during the relaxation or decompression phase to increase the magnitude and prolong the duration of negative intrathoracic pressure during the relaxation or decompression phase, i.e., respiratory muscle stimulation increases the duration and degree that the intrathoracic pressure is below or negative with respect to the pressure in the peripheral venous vasculature. By enhancing the amount of venous blood flow to the heart and lungs, cardiopulmonary circulation is increased.

Among the respiratory muscles that may be stimulated to contract are the diaphragm and the chest wall muscles, including the intercostal muscles. The respiratory muscles may be stimulated to contract in a variety of ways. For example, the diaphragm may be stimulated to contract by supplying electrical current or a magnetic field to various nerves or muscle bundles which when stimulated cause the diaphragm to contract. Similar techniques may be used to stimulate the chest wall muscles to contract. A variety of pulse trains, pulse widths, pulse frequencies and pulse waveforms may be used for stimulation. Further, the electrode location and timing of pulse delivery may be varied. In one particular aspect, an electrical current gradient or a magnetic field is provided to directly or indirectly stimulate the phrenic nerve.

To electrically stimulate the inspiratory motor nerves, electrodes are preferably placed on the lateral surface of the neck over the motor point for the phrenic nerve, on the chest surface just lateral to the lower sternum to deliver current to the phrenic nerves just as they enter the diaphragm, on the upper chest just anterior to the axillae to stimulate the thoracic nerves, in the oral pharyngeal region of the throat, or on the larynx itself. However, it will be appreciated that other electrode sites may be employed. For example, in one embodiment the respiratory muscles are stimulated by a transcutaneous electrical impulse delivered along the lower antero-lat margin of the rib cage. In one embodiment, inspiration is induced by stimulating inspiratory muscles using one or more electrodes attached to an endotracheal tube or pharyngeal tube.

A variety of other techniques may be applied to further enhance the amount of venous blood flow into the heart and lungs during the chest relaxation or decompression phase of CPR. For example, the chest may be actively lifted during the relaxation or decompression phase to increase the amount and extent of negative  
5 intrathoracic pressure. In another technique, air flow to the lungs may be periodically occluded during at least a portion of the relaxation or decompression phase. Such occlusion may be accomplished by placing an impedance valve into the patient's airway, with the impedance valve being set to open after experiencing a predetermined threshold negative intrathoracic pressure.

10 In one particular aspect of the method, respiratory gases are periodically supplied to the patient's lungs to ventilate the patient. In another aspect, a metronome is provided to assist the rescuer in performing regular chest compressions.

In still another aspect, the respiratory muscles are stimulated only during certain relaxation or decompression phases, such as every second or third relaxation or  
15 decompression phase. In yet another aspect, a defibrillation shock is periodically delivered to the patient to shock the heart or an electrical impulse is delivered to periodically initiate transthoracic pacing.

The invention further provides an exemplary device to assist in the performance of a cardiopulmonary resuscitation procedure. The device comprises a  
20 compression member which is preferably placed over the sternum and manually or mechanically pressed to compress the chest. At least one electrode is coupled to the compression member in a way such that the electrode will be positioned to supply electrical stimulation to the respiratory muscles to cause the respiratory muscles to contract following compression of the chest.

25 In one preferable aspect, a pair of arms extend from the compression member, with one or more electrodes being coupled to the end of each arm. Preferably, the arms are fashioned so as to be adapted to be received over the lower rib cage when the compression member is over the sternum. In this way, the electrodes are placed in a preferred location to stimulate the respiratory muscles to contract. Conveniently, the  
30 arms may be fashioned of a flexible fabric so that the arms will conform to the shape of the chest, thereby facilitating proper placement of the electrodes. In one preferable aspect, the electrodes comprise adhesive electrically active pads.

In one particular aspect, a voltage controller or a potentiometer is provided to control the stimulation voltage delivered to the electrode. In this way, a rescuer or a

closed loop feedback system may change the voltage output of the electrode to ensure adequate respiratory muscle stimulation. A metronome may optionally be provided and incorporated into the device to assist a rescuer in performing regular chest compressions with the compression member. In another aspect, the stimulation sites may be varied on a  
5 periodic basis with an automatic switching box to avoid respiratory muscle or chest wall muscle fatigue.

In one particularly preferable aspect, a pressure or force sensor is disposed in the compression member to sense when a compressive force is being applied to the compression member. Control circuitry may also provided to cause actuation of the  
10 electrode when the sensor senses an external compression that is being applied to the compressive member. In this way, a sensor-directed electrical impulse may be emitted from the electrode to transcutaneously stimulate the respiratory muscles to contract at the end of the compression phase. Endotracheal stimulation of respiration muscles is also possible in a similar manner. In cases where a significant delay occurs between delivery  
15 of the stimulant and full respiratory muscle contraction, the sensor may be employed to sense when mid-compression (or some other point in the compression phase) occurs to initiate respiratory muscle stimulation sometime before the start of the relaxation or decompression phase.

In still another aspect, a power source is coupled to the electrode. The  
20 power source may be integrally formed within the device or may be a separate power source which is coupled to the electrode. As another alternative, the electrode may be coupled to a defibrillator to provide a defibrillation shock or to initiate trans-thoracic cardiac pacing. In another aspect, the voltage controller and power source may be part of a sensor-compression-stimulation device or coupled to the device but separated from the  
25 compression-sensor-stimulation device. In still another alternative, the device may be coupled to a ventilator to periodically ventilate the patient based on the number of compressions. In another aspect, impedance or electrical impulses generated by chest compression may be sensed and used by a remote power source and pacer-defibrillation unit to stimulate respiratory muscle stimulation using the same sensing electrode(s) or  
30 other means to also stimulate the respiratory muscles to contract.

The invention further provides an exemplary device to assist in the performance of cardiopulmonary resuscitation by stimulating the phrenic nerve to cause the diaphragm or other respiratory muscles to contract during the relaxation or decompression phase of CPR. Such stimulation may be accomplished by delivering

either electrical or magnetic energy to the phrenic nerve. In one embodiment, the phrenic nerve stimulators may be coupled to a chest compression sensor to coordinate chest compressions with the electric or magnetic stimulation of the phrenic nerve. In another aspect, a signal, such as an audible signal or blinking light, may be produced each time  
5 electrical inspiration occurs, and manual chest compression is timed based on the emitted signal.

In another embodiment, the device comprises a ventilation member which is coupled to the patient's airway to assist in the flow of respiratory gases into the patient's lungs. A sensor may be coupled to the ventilation member to induce application of an  
10 electrical current to the phrenic nerve to cause the diaphragm or other respiratory muscles to contract. In this way, a ventilation member which is typically employed to provide ventilation to a patient during a CPR procedure may also function as a stimulant to cause contraction of the diaphragm or other respiratory muscles during the relaxation or decompression phase of CPR. In this manner, the amount of venous blood flowing to the  
15 heart and lungs will be enhanced.

A variety of ventilation members may be employed, including endotracheal tubes, laryngeal mask airways, or other ventilation devices which are placed within the larynx, esophagus, or trachea. In one particularly preferable aspect, a pair of electrodes is coupled to the ventilation member so that the device may operate in a  
20 unipolar or multipolar manner to stimulate the phrenic nerve. Other aspects include transcutaneous phrenic nerve stimulation with a collar-like device placed around the neck which includes one or more electrodes to stimulate the phrenic nerve.

In another embodiment, a system is provided to produce a cough. The system comprises at least one electrode that is adapted to be positioned on a patient to  
25 stimulate the abdominal muscles to contract. A valve is also provided and has an open position and a closed position. A controller is coupled to the electrode and the valve and is configured to open the valve while the electrode is actuated to cause the patient to cough. In one aspect, the controller is configured to open the valve for a time in the range from about 10 ms to about 500 ms after the abdominal muscles are stimulated to contract.

30 The invention further provides an exemplary method for increasing cardiopulmonary circulation when performing cardiopulmonary resuscitation on a patient in cardiac arrest. According to the method, at least some of the abdominal muscles are periodically stimulated to contract sufficient to enhance the amount of venous blood flow into the heart and lungs. In one aspect, the abdominal muscles may be electrically



stimulated to contract while preventing respiratory gases from exiting the lungs, and then permitting respiratory gases from exiting the lungs to produce a cough. In another aspect, the patient's chest is actively compressed during a compression phase and the patient's chest is permitted to rise during a decompression phase. Further, the abdominal muscles  
5 are stimulated to contract during a time period which ranges between a latter portion of the decompression phase to a mid portion of the compression phase.

### BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a top plan view of an exemplary respiratory muscle stimulation  
10 device according to the invention.

Fig. 2 is a side view of the device of Fig. 1.

Fig. 3 is a detailed bottom view of an end member of the device of Fig. 1 showing an electrode for stimulating the respiratory muscles.

Fig. 4 illustrates a top view of the end member of Fig. 3 showing a  
15 potentiometer, a metronome, and a power source.

Fig. 5 is a top plan view of an alternative embodiment of a respiratory muscle stimulation device according to the invention.

Fig. 5A illustrates yet another alternative embodiment of a respiratory muscle stimulation device according to the invention.

Fig. 6 is a schematic diagram of the circuitry of the device of Fig. 1  
20 according to the invention.

Fig. 7 illustrates the device of Fig. 1 when used to treat a patient according to the invention.

Fig. 8 illustrates an exemplary endotracheal tube having a pair of  
25 electrodes to electrically stimulate the phrenic nerve according to the invention.

Fig. 8A illustrates a collar to electrically or magnetically stimulate diaphragmatic stimulation according to the invention.

Fig. 8B illustrates the endotracheal tube of Fig. 8 having a plurality of electrodes disposed on an inflatable cuff according to the invention.

Fig. 9 is a schematic diagram of an exemplary system for stimulating the  
30 respiratory muscles to contract while performing CPR.

Fig. 10 illustrates a blanket having electrodes for stimulating the respiratory muscles to contract according to the invention.

Fig. 11 schematically illustrates a system for stimulating the abdominal muscles according to the invention.

Fig. 12 illustrates a system for respiratory gas occlusion and abdominal stimulation according to the invention.

5 Fig. 12A illustrates a facial mask of the system of Fig. 12.

Fig. 12B illustrates an endotracheal/abdominal stimulation system according to the invention.

#### DESCRIPTION OF THE SPECIFIC EMBODIMENTS

10 The present invention provides methods and devices for increasing cardiopulmonary circulation when performing cardiopulmonary resuscitation. As is known in the art, cardiopulmonary resuscitation techniques involve a compression phase where the chest is compressed and a relaxation or decompression phase where the chest is allowed to return to its normal position. The methods and devices of the invention may  
15 be used in connection with any method of CPR in which intrathoracic pressures are intentionally manipulated to improve cardiopulmonary circulation. For instance, the present invention may be used in connection with standard, manual, closed-chest CPR, interposed abdominal counterpulsation CPR, with a mechanical resuscitator, such as the Michigan Instruments "Thumper", with ACD-CPR, with "Lifestick" CPR, and the like.  
20 In addition, certain embodiments may be used to induce inspiration and/or coughing. This may help to maintain blood pressure during cardiac arrest and may help patients that are incapable of voluntary inspiration or coughing.

In a broad sense, one aspect of the present invention provides for stimulating contraction of at least some of the respiratory muscles during the relaxation or  
25 decompression phase of CPR to enhance and sustain the duration of negative intrathoracic pressure during the relaxation or decompression phase. The significance of the increase in negative intrathoracic pressure during the relaxation or decompression phase is that more venous blood is forced into the chest from the peripheral venous vasculature. As a result, more blood is allowed to be oxygenated and more blood is forced out of the chest  
30 during the next compression. Upon contraction of the respiratory muscles, the patient will typically "gasp". The invention thus provides techniques for consistently inducing a "gasp" after chest compression.

The decrease in intrathoracic pressure produced by electrical stimulation of the inspiratory muscles, including the diaphragm, during the chest relaxation phase of

CPR is associated with an increase in coronary perfusion pressure and thus an increase in blood flow to the heart. The coronary perfusion pressure to the heart during the decompression phase can be calculated by the mathematical difference between the aortic and right atrial pressure. Right atrial pressure is lowered by inspiratory effort, and  
5 therefor the aortic-right atrial gradient or the coronary perfusion pressure is increased by stimulation of inspiratory effort.

The respiratory muscles that may be stimulated to contract to enhance ventilation and/or to alter intrathoracic pressures include the diaphragm, the chest wall muscles, including the intercostal muscles and the abdominal muscles. Specific chest  
10 wall muscles that may be stimulated to contract include those that elevate the upper ribs, including the scaleni and sternocleidomastoid muscles, those that act to fix the shoulder girdle, including the trapezii, rhomboidei, and levatores angulorum scapulorum muscles, and those that act to elevate the ribs, including the serrati antici majores, and the pectorales majores and minores as described generally in Leslie A. Geddes,  
15 "Electroventilation - A Missed Opportunity?", Biomedical Instrumentation & Technology, July/August 1998, pp. 401-414, the complete disclosure of which is herein incorporated by reference. Of the respiratory muscles, the two hemidiaphragms and intercostal muscles appear to be the greatest contributors to inspiration and expiration.

The invention provides a variety of ways to stimulate respiratory muscle  
20 contraction so that the magnitude and extent of negative intrathoracic pressure during the relaxation or decompression phase may be increased. Preferably, the respiratory muscles are stimulated to contract by transcutaneous or transtracheal electrical field stimulation techniques. For example, to stimulate the diaphragm, the phrenic nerve may be stimulated in the neck region near C3, C4 or C5, or where the phrenic nerves enter the  
25 diaphragm. Alternative techniques for stimulating diaphragmatic contraction include magnetic field stimulation of the diaphragm or the phrenic nerve. Magnetic field stimulation may also be employed to stimulate the chest wall muscles. Electrical field stimulation of the diaphragm or the chest wall muscles may be accomplished by placing one or more electrodes on the skin, preferably in the vicinity of the neck or the lower rib  
30 cage (although other locations may be employed) and then providing an electrical voltage gradient between electrodes that induces transcutaneous current flow to stimulate the respiratory muscles to contract. Still further, subcutaneous electrodes may also be used to stimulate respiratory muscle contraction.

In another broad aspect of the invention, venous return may be enhanced by compressing the abdomen. For example, downward compression provided to the abdomen causes the diaphragm to move upward into the thoracic cavity. As the abdomen is compressed, venous blood is physically forced out of the abdominal cavity and into the thoracic cavity. Advantageously, when the abdomen is compressed, there is an increase in resistance to the flow of blood from the thoracic aorta into the abdominal aorta. This gradient causes a greater proportion of arterial blood flowing to the brain and to the heart. In one aspect, abdominal compression may start during the second half of the decompression phase and last until the compression phase or about half way through the compression phase. The use of abdominal compression during CPR is described generally in J. M. Christenson, et. al., "Abdominal Compressions During CPR: Hemodynamic Effects of Altering Timing and Force", The Journal of Emergency Medicine, Vol 10, pp 257-266, 1992, the complete disclosure of which is herein incorporated by reference.

According to the invention, one way to contract the abdominal muscles is by electrical stimulation. For example, one or more electrodes may be positioned on the abdominal area at a variety of locations, including the back. Hence, the abdominal muscles may be made to contract at specific time intervals in relation to chest compression and/or inspiratory muscle electrical stimulation. As the abdominal muscles are electrically stimulated, the abdominal cavity squeezes to force the diaphragm upward into the thoracic cavity. Also, venous blood is moved from the abdomen to the thorax, and right atrial pressures increase. In this manner, venous blood is actively transported to the thorax. Further, when abdominal compression extends into the compression phase of CPR, exhalation is transformed from a passive to a more active process. Further, an increase in coronary perfusion pressure is obtained.

The techniques employed to stimulate the inspiratory muscles and/or nerves and to stimulate the abdominal muscles may be utilized either alone or in combination. These stimulation techniques may also be used with or without active chest compression. For example, even in the absence of active chest compression, large swings in intrathoracic pressure induced by electrical stimulation of the inspiratory muscles and/or nerves either alone or concomitantly with abdominal musculature stimulation will enhance vital organ perfusion and increase the chances for resuscitation.

The inspiratory muscles and/or nerves are preferably stimulated to contract immediately after the chest is compressed. Preferably, the inspiratory muscles and/or

nerves are stimulated in a manner such that as soon as the compression phase is over, the intrathoracic pressure falls secondary to electrical stimulation of the inspiratory muscles. The compression phase may be configured to last approximately 50% of the CPR cycle. However, in some cases it may be desirable to shorten the compression phase and  
5      lengthen the decompression phase to further enhance venous return.

Abdominal compression and/or abdominal musculature stimulation may occur mid-way through the decompression phase and continue through at least the beginning of the compression phase. As previously described, at the end of the compression phase, intrathoracic pressure is lowered to enhance venous blood return.  
10      This may be augmented by causing the respiratory muscles, including the diaphragm, to contract. As the abdomen is compressed or the abdominal muscles are stimulated to contract mid-way through the decompression phase, the diaphragms are pushed actively upward into the thorax to force respiratory gases out of the chest and venous blood is forced into the thorax. When the compression phase is reached and the abdomen is still  
15      contracted, there is an increase in resistance to the flow of blood from the thoracic aorta into the abdominal aorta. This gradient causes a greater proportion of arterial blood flowing to the brain and to the heart.

In one aspect of the invention, the abdominal muscles may be stimulated sequentially in a valve-like manner so as to squeeze venous blood out of an area. For  
20      example, two electrodes may be spaced-apart from each other to form an electrode pair. Multiple pairs may be positioned lengthwise on the patient. The pairs of electrodes may be sequentially actuated, beginning from a bottom pair, to force blood out of the abdominal area into the thoracic cavity. Alternating the pattern in which the electrodes are actuated may help to prevent muscle fatigue.

25      The respiratory and abdominal muscle stimulation techniques of the invention may be used in connection with or in close association with various other techniques designed to treat or diagnose the patient receiving CPR. For example, during the relaxation or decompression phase, the patient's airway may be occluded to prevent foreign (outside) air or respiratory gases from flowing to the patient's lungs. In this way,  
30      the magnitude and duration of negative intrathoracic pressure during the relaxation or decompression phase are further enhanced. Exemplary devices and methods for occluding the patient's airway during the relaxation or decompression phase are described in U.S. Patent Nos. 5,551,420 and 5,692,498 and co-pending U.S. Application Serial No. 08/950,702, previously incorporated herein by reference. As another example, the

respiratory muscle stimulation techniques of the invention may be used in connection with ACD-CPR where the patient's chest is actively lifted during the relaxation or decompression phase to further enhance and sustain the duration of negative intrathoracic pressure during the relaxation or decompression phase.

5           The electrodes employed by the invention to stimulate respiratory muscle contraction may optionally be coupled to a defibrillator to deliver a defibrillation shock to the heart, or to supply energy to initiate transthoracic or transhacheal cardiac pacing. Since the device is preferably in contact with the skin, the device may optionally include various sensors to monitor various physiological parameters. For example, the device  
10   may include oxygen sensors, temperature sensors, or sensors to monitor O<sub>2</sub> saturation. Further, sensors may be provided to sense surface cardiac electrograms. The device may also be employed to deliver drugs transcutaneously.

          In one embodiment, an adhesive compressive pad is placed over the lower portion of the sternum. Compressions are applied as with standard manual CPR to a  
15   depth of about two to three inches. A sensor is incorporated in a compression region of the pad and is employed to signal the triggering of respiratory muscle contraction. Preferably, portions of the compressive pad are electrically active to stimulate diaphragmatic and/or chest wall muscle contraction upon receipt of a signal from the sensor. In one aspect, the stimulator may emit a signal, such as an audible signal, a visual  
20   signal or the like, allowing the rescuer to time chest compressions based on the emitted signal.

          Referring now to Figs. 1 and 2, an exemplary embodiment of a device 10 to provide respiratory muscle contraction during the performance of CPR will be described. Device 10 comprises a compression member 12 which is configured so that it  
25   may be received over the patient's chest in the area of the sternum. In this way, compression member 12 may be pressed downward to compress the patient's chest during the compression phase of CPR. Coupled to compression member 12 by a pair of arms 14 and 16 are a pair of end elements 18 and 20, respectively. As best shown in Fig. 3, end element 18 includes an electrode 22 on a bottom surface, it being appreciated that end  
30   element 20 or compression member 12 may include a similar electrode. Electrode 22 may comprise an adhesive electrically active pad, such as an R2 pad, commercially available from 3M. Electrodes 22 may also include a conductive gel. Other electrodes that may be employed include electrodes constructed of stainless steel, carbon-filled silicone rubber, platinum, iridium, silver silver-chloride, and the like. The electrode may

be applied to the skin surface or may pierce the skin surface. It will also be appreciated that electrode 22 may be configured to operate in a monopolar manner, a bipolar manner or a multipolar manner. Further, electrode 22 may be configured to deliver electrical stimulation at different frequencies, pulse widths, pulse trains and voltage outputs to  
5 optimize respiratory muscle stimulation. The configuration of arms 14 may be varied to vary the lead vector produced by electrode 22. For example, the lead vector may be from one side of the chest to the other, to the midcompression region, or from one lead to the other on the same side of the chest. Device 10 may also be configured to deliver an output based, at least in part, upon the chest wall impedance. An energy source is  
10 coupled to the electrodes to deliver low energies, e.g., less than about 2 amps, to stimulate the respiratory muscles.

Although electrodes 22 have been described as electrodes which provide electrical stimulation, it will be appreciated that device 10 can be modified to provide a magnetic field to stimulate the respiratory muscles to contract. For example, a magnetic  
15 field may be applied to the phrenic nerve to produce diaphragmatic and/or chest wall muscle stimulation. As such, an upper back pad may be needed for optimal phrenic nerve stimulation.

Exemplary techniques for stimulating the respiratory muscles, and particularly the diaphragm, to contract, including techniques for providing both electrical  
20 and magnetic stimulation of the inspiratory motor nerves, are described in L.A. Geddes, "Electrically Produced Artificial Ventilation," Medical Instrumentation 22(5): 263-271 (1988); William W.L. Glenn et al., "Twenty Years of Experience in Phrenic Nerve Stimulation to Pace the Diaphragm," Pace 9:780-784 (November/December 1986, Part 1); P.L. Kotze et al., "Diaphragm Pacing in the Treatment of Ventilatory Failure," Sant.  
25 Deel 68:223-224 (August 17, 1995); L.A. Geddes et al., "Inspiration Produced by Bilateral Electromagnetic, Cervical Phrenic Nerve Stimulation in Man," IEEE Transactions on Biomedical Engineering 38(9):1047-1048 (October 1991); L.A. Geddes et al., "Optimum Stimulus Frequency for Contracting the Inspiratory Muscles with Chest-Surface Electrodes to Produce Artificial Respiration," Annals of Biomedical Engineering  
30 18:103-108 (1990); Franco Laghi et al., "Comparison of Magnetic and Electrical Phrenic Nerve Stimulation in Assessment of Diaphragmatic Contractility," American Physiological Society, pp. 1731-1742 (1996); and William W.L. Glenn et al., "Diaphragm Pacing by Electrical Stimulation of the Phrenic Nerve," Neurosurgery 17(6):974-984 (1985). The complete disclosures of all these references are herein incorporated by

reference in their entirety. The electrodes of the invention may be configured to operate in a monopolar manner, a bipolar manner, or a multi-polar manner.

Arms 14 and 16 are preferably constructed of a flexible material, including fabrics, such as a nylon fabric, elastomeric materials, including rubbers, plastics and the like, to facilitate proper placement of electrodes 20 on the patient. Optionally, arms 14 and 16 may be pivotally attached to compression member 12 to allow electrodes 20 to be placed at a variety of locations on the patient.

As illustrated in Fig. 4, a top side of end element 18 includes a metronome 24. Metronome 24 assists the rescuer in performing regular chest compressions when performing CPR by emitting regular audible or visual signals. This, in turn, aids in the coordinated timing between the compression of the chest and the stimulation of the respiratory muscles during the relaxation or decompression phase. End element 18 further includes a voltage controlling mechanism, such as a potentiometer 26, which enables the rescuer to change the voltage output of electrode 22 (see Fig. 3) to ensure adequate diaphragmatic stimulation. In one alternative, proper voltage may be determined automatically depending upon chest wall impedance that is measured with an impedance meter. In this way, device 10 may be configured so that it does not over stimulate or under stimulate the inspiratory motor nerves. End element 18 still further includes an energy source 28 which provides energy to the various electrical components, sensors, impedance meters, electrodes, and the like of device 10. Energy source 28 may conveniently comprise a battery that is stored within end element 18. Alternatively, a wide variety of external energy sources may be employed to operate device 10. For example, electrical energy may be provided by a ventilator which is employed to ventilate the patient, a defibrillator which may optionally be employed to provide defibrillation and transthoracic cardiac pacing and house the electrical components of a sensing system, an electrical generator which converts mechanical energy provided by the rescuer during compression of compression member 12 to electrical energy, and the like.

Although not shown, device 10 may optionally include a variety of displays, instructions for use, and controls that may be located on compression member 12, arms 14 or end elements 18. For example, device 10 may include a force, pressure or depth display which displays the amount of force, pressure or depth being applied to compression member 12 by the rescuer. In this way, the rescuer may be provided with information regarding the amount of force being supplied to compression member 12. Preferred force ranges may be included on device 10 so that the rescuer may determine if



he is within a recommended force range. Device 10 may also include a compression counter display which displays the number of compressions experienced by compression member 12. The compression counter may be configured to display cycles of compressions to allow the rescuer to visualize the number of compressions that are performed for every respiratory muscle stimulation. Device 10 may still further include a surface electrogram sensing display to display information relating to a surface electrogram. Still further, a physiological parameter display may be provided to display various physiological parameters such as O<sub>2</sub> saturation, CO<sub>2</sub> saturation, skin temperature, and the like.

As shown in Fig. 5, device 10 may be provided with a wishbone configuration so that end elements 18 are placed over the lower margin of the rib cage. Arms 14 and 16 may be configured to be fixedly mounted relative to compression member 12 so that the electrodes will always be placed at about the same region on the chest. Alternatively, arms 14 and 16 may be movably mounted to compression member 12 so that the position of the electrodes on the patient may be adjusted. As previously described, arms 14 and 16 may be configured to be constructed of either a flexible or a rigid material to facilitate proper placement of the electrodes on the patient.

In another embodiment illustrated in Fig. 5A, a device 10' is provided which is similar to device 10 of Fig. 5 (with similar elements being labeled with the same reference numerals) and further includes an arm 14a having an end element 18a which is placed over the left axilla and has an electrode for defibrillation between the arm and the chest. In this way, compression member 12 may be placed over the sternum, with end elements 18 and 20 being placed over the lower rib cage to stimulate the respiratory muscles to contract between chest compressions as previously described. When needed, defibrillation may be provided by actuating the electrode on end element 18a. Optionally, a defibrillation unit 52a may be coupled to device 10'. Unit 52a includes an energy source for both diaphragmatic pacing and defibrillation. In this way, the energy source and other electrical components may be included within device 10' or in unit 52a.

Referring now to Fig. 6, a schematic diagram of the electrical components employed with device 10 will be described. Electrical power is provided to the various components with a circuit supply voltage module 30. Module 30 corresponds to energy source 28 of Fig. 4 and may comprise an internal or external power supply as previously described. A compression sensor and force display module 32 is provided to sense compression of compression member 12 (see Fig. 1) and to optionally display the force,

pressure, and/or depth information to the rescuer. Exemplary compression sensors that may be employed include piezoelectric crystals that produce an electrical charge in proportion to the amount of force applied, fluid reservoirs and associated pressure sensors to detect an increase in pressure upon application of a force, strain gauges, and the like.

- 5 Conveniently, the force detected by the compression sensor may be displayed on an LCD, LED or other display on device 10.

A compression counter/display and signal control module 34 is coupled to compression sensor 32 and counts each compression of compression member 12. The number of compressions may conveniently be displayed on device 10. Signals from  
10 module 34 are also transferred to a stimulation control and pulse sequence generator module 36 which is responsible for producing electrical signals employed by electrodes 22 (see Fig. 3). Module 36 is configured to produce an electrical pulse immediately after receipt of a counting logic signal from module 34. In this way, the electrodes may be actuated immediately after the compressive force is applied by the rescuer so that  
15 respiratory muscle stimulation is triggered to occur at the beginning of the relaxation or decompression phase of CPR. Module 36 preferably includes a signal generator to produce pulsed sequences resulting in the delivery of energy through the electrodes. Module 36 may be configured to produce pulses which correlate to every signal received from module 34 or only for selected signals from module 34. In this way, respiratory  
20 muscle stimulation may occur immediately after every compression or only after certain compressions.

In electrical communication with module 36 is a high voltage module 38 which functions to provide high voltage waveforms so that the electrodes may operate at the proper stimulation voltage level. Module 38 may be employed to operate the  
25 electrodes to provide respiratory muscle stimulation as shown. The applied voltage may be modified by the rescuer by operating potentiometer 26 (see Fig. 4). Additionally, module 38 may be employed to operate the electrodes so that they perform a defibrillation function or to accomplish transthoracic cardiac pacing as is known in the art. In this way, device 10 may be used to stimulate the respiratory muscles to contract during CPR as  
30 well as for cardiac defibrillation or transthoracic cardiac pacing.

Also in electrical communication with module 34 is a ventilation control module 40. Module 40 is optional and may be provided to receive electrical signals from module 34 indicating actuation of compression sensor 32. Module 40 is coupled to a ventilation device 42 which may be configured to periodically ventilate the patient in an

automated manner based on actuation of compression sensor 32 as CPR is being performed. Preferably, module 40 will be configured to actuate the ventilator at a frequency of about one ventilation to every five compressions. As one example, control module 40 may be constructed similar to the module described in U.S. Patent No. 4,397,306 to coordinate the actuation of ventilation device 42 with actuation of compression sensor 32. The complete disclosure of this reference is herein incorporated by reference. Although device 10 has been described as being coupled to an automated ventilation device, it will be appreciated that manual ventilation devices and techniques may also be employed to ventilate the patient during the performance of CPR, whether or not electrically coupled to device 10. One advantage of providing ventilation control module 40 is that ventilation device 42 and high voltage control module 38 are electrically coupled so that coordination of ventilation, diaphragmatic pacing, cardiac pacing, and/or defibrillation may occur.

Device 10 may be modified so that the electrical components (such as those set forth in Fig. 6) and power source are provided in a separate unit. For example, such components may be incorporated into a defibrillator which in turn is coupled to device 10. In this way, device 10 may be manufactured relatively inexpensively, with the electrical components being provided in a separate unit. Further both diaphragmatic stimulation and pacing may be provided with a base unit which is coupled to device 10.

In one particular alternative, patient ventilation may be assisted with the use of a ventilation device having a threshold negative intrathoracic pressure device which opens when a predetermined negative intrathoracic pressure is reached during the relaxation or decompression phase as described in U.S. Patent Nos. 5,692,498 and 5,551,420, previously incorporated by reference. With such a configuration, device 10 may be provided with a controller which is coupled to the threshold valve so that actuation of the threshold valve may be coordinated with diaphragmatic stimulation to optimize the negative intrathoracic pressure. In particular, the impedance threshold valve may be opened and closed using a servo- or electromagnetically-controlled circuit that is coupled to device 10 so that its operation may be coordinated with operation of the electrodes.

Still referring to Fig. 6, a metronome timing display module 44 is electrically coupled to circuit supply high voltage module 30 and is employed to produce regular audible and/or visual signals to assist the rescuer in performing regular chest compressions. A surface electrogram sensing/display module 46 is also electrically

coupled to module 30 and allows for the sensing of surface electrograms and displaying the sensed information. Exemplary sensors for sensing surface electrograms include needles that are inserted through the skin, electrode-gel coupled sensors, and the like. A gas sensing display module 48 is provided to sense and display the amount of various gases in a patient's blood, airway, or skin/cutaneous surface. For example, module 48 may be employed to sense the amount of oxygen saturation, CO<sub>2</sub> saturation, and the like. Optionally, module 48 may include a thermistor or thermocouple-based temperature measuring device that may be placed against or inserted into the skin to measure the patient's body temperature.

10 A drug delivery control module 50 may optionally be provided to supply various drugs to the patient. For example, module 50 may be a passive device for delivering nitroglycerine. Alternatively, module 50 may be an active device for electrophoretic delivery of drugs such as vasopressin, an anti-arrhythmic drug, and the like. In this way, module 50 provides device 10 with the ability to transcutaneously  
15 deliver drugs as device 10 is placed against the patient's body to perform CPR.

Although one embodiment illustrates the use of a compression member to sense when the chest is being compressed, it will be appreciated that other techniques may be provided to sense chest compression. For example, electrodes may be placed on the chest and sensors employed to detect electrical impulses or a change in impedance as  
20 the chest is compressed. Alternatively, a pressure sensor may be provided in an airway device to detect an increase in airflow in the patient's airway. The electrodes may be coupled to an external defibrillator-pacer that is capable of delivering low energies, i.e. about 0.01 amps to about 2 amps, and more preferably about 0.1 amps to about 2.0 amps, to stimulate the diaphragm or other respiratory muscles. In this way, a system is provided  
25 which may provide respiratory muscle stimulation (that is coordinated with chest compressions), pacing, and defibrillation.

Referring now to Fig. 7, an exemplary method for performing CPR using device 10 will be described. As shown, device 10 is placed on the patient such that compression member 12 is placed over the sternum and end elements 18 and 20 are  
30 placed over the ribs. As previously described, the particular location and arrangement of end elements 18 and 20 may be varied to optimize respiratory muscle stimulation. The rescuer then compresses compression member 12, preferably by placing both hands on compression member 12 and pushing downward. Compression of compression member 12 proceeds in a manner similar to that performed when performing traditional CPR.

Immediately after the maximum compression is applied, electrodes on end elements 18 and 20 are actuated to stimulate the diaphragm and/or the chest wall muscles to contract during the relaxation or decompression phase. Conveniently, power is supplied to the electrodes via an external defibrillator 52, although other energy sources may be employed as previously described. The electrodes may be actuated during every relaxation or decompression phase or during only selected relaxation or decompression phases, depending on the need of the patient. Since device 10 is coupled to the defibrillator 52, the patient may also be supplied with a defibrillation shock or cardiac pacing. Hence, defibrillator 52 may be used to stimulate respiratory muscle contraction as well as to pace and/or defibrillate the heart. In that case, the sensor may be configured to be the same electrodes used to defibrillate the patient so that no compression member would be needed.

To stimulate respiratory muscles contract, the current supplied by the electrodes is preferably in the range from about 0.01 amps to about 2.5 amps, and more preferably from about 0.1 amps to about 1.0 amps. However, it will be appreciated that the specific amount of current will depend on chest wall impedance and mode of stimulation, e.g., square wave impulse, unipolar wave forms, biphasic wave forms, multiphasic wave forms, multi-vectorial pathways, use of pulse trains, and the like. In some cases it may be desirable to stimulate one side of the diaphragm or chest wall at a different time from the other side of the diaphragm or chest wall, e.g., by about 10 msec to about 200 msec, to reduce the risk of shock to the rescuer and to reduce inspiratory muscle fatigue. The respiratory muscles may be stimulated to contract at a frequency in the range from about 30 to about 120 times per minute. The timing sequence for stimulating different chest wall or other sites to induce inspiratory muscle contraction may be alternated to avoid muscle fatigue by varying the amplitude and duration of stimulation based upon a resistance or impedance measurement at any given stimulation site. Resistance measurements may be used in a closed loop circuit to help vary stimulation site location and stimulation outputs.

Periodically, about every two to ten compressions, the patient is ventilated. Ventilation may be accomplished using an automated ventilator which may or may not be coupled to device 10. Alternatively, various manual ventilators may be employed as is known in the art. In one particular embodiment, a ventilation device is coupled with a threshold valve so that the duration and extent of negative intrathoracic pressure may be controlled during the relaxation or decompression phase as previously described. A

pressure sensor and feedback loop circuit may also be used to measure the negative intrathoracic pressure in the airway and adjust the energy delivered to the electrode to maintain a generally constant negative intrathoracic pressure caused by each contraction of the respiratory muscles.

5 Referring now to Fig. 8, an alternative embodiment of a device 54 for stimulating the respiratory muscles to contract will be described. Device 54 comprises an endotracheal tube 56 having an inflatable member 58 (shown in phantom line) which serves to secure endotracheal tube 56 in the patient's airway as is known in the art. Endotracheal tube 56 includes a lumen 60 through which the patient is ventilated. Device  
10 54 further includes a pair of electrodes 62 and 64 which operate in a bipolar manner to electrically stimulate the phrenic nerve, although other numbers and arrangements of electrodes may be employed, including monopolar electrode configurations. Electrode 62 or a plurality of electrodes may also be attached to inflatable cuff 58 as shown in Fig. 8B. In turn, stimulation of the phrenic nerve causes the diaphragm and chest wall muscles to  
15 contract. An electrical lead 66 is provided to supply electrical current to electrode 62.

In this way, when device 54 is inserted into the patient's airway, electrodes 62 and 64 are positioned so that when current is supplied to electrode 62, the phrenic nerve is electrically stimulated to cause the diaphragm muscles to contract. As with other embodiments described herein, electrode 62 is preferably actuated during the relaxation  
20 or decompression phase of CPR so that the respiratory muscles contract to increase the magnitude and extent of negative intrathoracic pressure during the decompression phase. Optionally, lead 66 may be coupled to a controller of a compression device which is similar to compression member 12 so that electrical stimulation of the phrenic nerve may be coordinated with chest compression. In a similar manner, lead 66 may be coupled to a  
25 ventilator which supplies air through lumen 60 so that ventilation may also be coordinated in a manner similar to that described with previous embodiments. Further, an impedance valve may be coupled to the endotracheal tube as described in U.S. Patent Nos. 5,551,420 and 5,692,498, previously incorporated by reference.

In another alternative, endotracheal tube 54 may be provided with  
30 electrodes to also pace the heart. Such electrodes may be configured in a bipolar or monopolar manner, and may optionally be connected with an external electrode or an esophageal electrode.

Although described in the context of an endotracheal tube, it will be appreciated that electrical stimulation of the phrenic nerve may be accomplished by

placing electrodes on a laryngeal mask airway, or other ventilation device which is placed within the larynx, esophagus, or trachea. Further, one or more electrodes may be included on a laryngeal mask airway or endotracheal tube that is inserted into the esophagus to pace the heart and/or to stimulate the phrenic nerve. As one example, such an electrode may be placed on an airway as described in U.S. Patent No. 5,392,774, the disclosure of which is herein incorporated by reference. As another alternative, an electrical stimulator may be placed externally over the neck to stimulate the phrenic nerve. In still a further alternative, a magnetic field may be produced about the phrenic nerve to stimulate the diaphragm or chest wall muscles to contract. Devices for producing such an electrical field may be placed within the airway or externally about the neck.

One particular embodiment of a device 200 for either electrically or magnetically stimulating the phrenic nerve is illustrated in Fig. 8A. Device 200 comprises a collar having one or more electrodes or elements to produce electrical current or a magnetic field to stimulate the phrenic nerve. Device 200 is coupled to a controller 202 having a power source. Also coupled to controller 202 is a compression sensor 204 so that respiratory muscle stimulation may be coordinated with chest compressions as previously described.

In one particular embodiment, the invention may employ the use of a mechanical chest compressor which is coupled to a ventilator as described in U.S. Patent No. 4,397,306, previously incorporated by reference. The stimulating electrodes may be coupled to the chest compressor or ventilator via a controller so that the controller may coordinate chest compression, ventilation, respiratory muscle stimulation, defibrillation, pacing, as well as other features previously described. Further, the amount of negative intrathoracic pressure generated with each contraction of the respiratory muscles may be used to adjust the energy needed for subsequent contractions. Such a system may conveniently be located in an emergency vehicle or a health care facility.

For example, one such system 100 is illustrated schematically in Fig. 9 and comprises a compression piston 102 that is held over a patient's thorax 104 by a support arm 106. Compression piston 102 is powered by an electric or pneumatic motor 108. When in use, piston 102 moves downward to compress the patient's chest. After the compression phase is complete, a spring 110, or other return mechanism, lifts piston 102 from the patient's chest to maximize the negative intrathoracic pressure during the relaxation phase. A controller is included with motor 108, and piston 102 includes a

sensor 112 so that the respiratory muscles may be triggered to contract during the relaxation or decompression phase. The controller may optionally be coupled to a ventilator, a defibrillator, a heart pacer, a drug delivery system, various other sensors and/or an airway occluding device as previously described.

5                Still another embodiment of a device 300 for stimulating the respiratory muscles to contract is illustrated in Fig. 10. Device 300 comprises an insulated blanket 302 which is constructed of an electrically insulative material, such as rubber, to protect the rescuer against possible shocks. Blanket 302 may incorporate any of the elements of other embodiments described herein to assist in respiratory muscle stimulation,  
10    monitoring, drug delivery, sensing, defibrillation, pacing, and the like. For example, blanket 302 includes electrodes 304 which may be selectively located to stimulate respiratory muscle stimulation. For example, electrodes 304 may be placed over the lower margin of the rib cage as previously described, or over the abdomen to stimulate the abdomen. A compression sensor 306 is provided to coordinate chest compressions  
15    with activation of electrodes 304. A potentiometer 308 is included to regulate the amount of current supplied by electrodes 304. A power supply 310 is further provided to supply current to electrodes 304.

Referring now to Fig. 11, a stimulation system 320 will be described. System 320 includes multiple leads 322 – 332 that are arranged in pairs. Although shown  
20    with six leads, it will be appreciated that other numbers and arrangements may be employed. For example, leads may be placed onto the patient's back. Leads 322 – 332 are arranged so that pairs of the leads may be sequentially actuated to produce a wave of contractions forcing venous blood back into the thorax and causing the diaphragm to be pushed upward to lead to respiratory gas exhalation. For example, leads 330 and 332  
25    may first be actuated, followed by actuation of leads 326 and 328, and followed by actuation of leads 322 and 324.

The leads are coupled to a controller/power source 334 to supply current to the leads and to control when the leads are actuated. Conveniently, controller 334 may be configured similar to the controllers and/or other electrical circuitry that are associated  
30    with the various inspiratory muscle stimulator systems described herein. In some cases, controller 334 may be incorporated into or coupled with these inspiratory stimulation controllers and/or electrical circuitry to coordinate alternating inspiratory muscle and abdominal musculature contraction. Further, such a controller may be configured to control the timing sequence of the leads so that the abdominal stimulation occurs about



half way into the inspiratory muscle stimulation phase. This typically occurs about half way into the chest wall decompression phase when chest compressions are performed.

Figs. 12, 12A and 12B illustrate devices or systems used to simultaneously cause an increase in intra-abdominal pressure and transient airway occlusion to induce an electrical cough, thereby promoting blood out of the chest to the brain and out of the abdomen to the chest. When performed in connection with chest compressions, cardiac output is maintained by rhythmically increasing intrathoracic pressure against a closed airway with a simultaneous increase in abdominal pressure. Upon release of the abdominal stimulation and expiratory airway occlusion, followed by passive or active downward movement of the diaphragm, the chest is filled with air and both ventilation and cardiopulmonary circulation is induced.

Shown in Fig. 12 is a system 350 to produce a cough by periodic occlusion of respiratory gases and by abdominal stimulation. System 350 includes a respiratory face mask 352 having a pressure release valve 353 to transiently prevent respiratory gases from exiting the lungs to raise intrathoracic pressure. System 350 further includes one or more stimulation electrodes 354 that may be employed to stimulate inspiratory effort similar to that described with previous embodiments. Although shown on the abdomen, it will be appreciated that electrodes may be placed at other locations, such as on the neck or chest, to also stimulate the diaphragm to contract. Positioned between electrodes 354 and release valve 353 is a controller 356. In this way, opening of release valve 353 may be coordinated with actuation of electrodes 354. Also shown in Fig. 12 is a chest compression site 358 to indicate where chest compressions may optionally be performed. System 350 may optionally include a respiratory air bag 360 to periodically ventilate the patient.

In use, valve 353 is closed to prevent respiratory gases from exiting the patient. Electrodes 354 are actuated to increase intra-abdominal pressure. During stimulation of the abdominal muscles, valve 353 is abruptly opened to induce the patient to cough. In one aspect, valve 353 may be opened for a time in the range from about 10 ms to about 500 ms after the abdominal muscles are stimulated to contract. After coughing, air bag 360 may be used to ventilate the patient. Chest compressions and/or respiratory muscle stimulation may optionally be performed prior to each induced cough.

Referring now to Fig. 12A, mask 352 will be described in greater detail. Coupled to mask 352 are a pair of straps 362 that may be secured together about the patient's head to seal mask 352 to the patient's face. Conveniently, a material, such as

Velcro, may be employed to hold the straps together. Extending from mask 352 is an expiration tube 366 which is coupled to valve 353. Also coupled to valve 353 is a connector 368 to allow valve 353 to be coupled to controller 356. Valve 353 may include an actuator that runs on DC voltage so that when an electrical signal is sent from controller 356, valve 353 is opened. Valve 353 further includes an expiratory gas port 368 to allow respiratory gases from the patient to be exhaled once valve 353 is opened.

Mask 352 also includes a pressure transducer port 370 which may include a pressure transducer so monitor the pressure within the patient. The transducer may be coupled to controller 356 (see Fig. 12) so that the pressure may be monitored. Mask 352 may further includes a safety pressure release check valve 372 that may be configured to open if the intrathoracic pressure becomes too great. Coupled to tube 366 is a ventilation bag valve connector 374 that allows air bag 360 (see Fig. 12) to be coupled to mask 352.

Fig. 12B illustrates an endotracheal/abdominal stimulation system 376. System 376 includes one or more electrodes 378 positioned on the abdomen to stimulate the abdominal muscles. An endotracheal tube 380 is also provided with one or more electrodes 382 to stimulate the diaphragm to contract. A controller 384 is provided to control actuation of both electrodes 378 and 382. In this way, diaphragmatic stimulation may be alternated with abdominal stimulation. Alternatively, a chest compression site 386 may be provided. However, external chest compressions may not be needed once an alternating inspiratory/abdominal muscle stimulation pattern is established. System 376 may optionally include a valve system 388. Valve system 388 may include a pressure release valve similar to valve 353 of Fig. 12A to induce the patient to cough. Valve system 388 may optionally include a threshold impedance valve and/or a threshold expiration valve similar to the valves described in U.S. Patent Nos. 5,551,420 and 5,692,498 to augment negative and/or positive negative intrathoracic pressures. In this way, large increases and/or decreases in intrathoracic pressures may be obtained. System 376 may also optionally include a respiratory bag 390 to periodically supply respiratory gases to the patient.

Hence, in one aspect, the invention may utilize either the face mask system of Fig. 12 or the endotracheal tube system of Fig. 12B to periodically block the release of respiratory gases or to periodically block both expiratory and inspiratory gases. This may be done in combination with abdominal and/or diaphragmatic muscle stimulation. Chest compressions may also be performed, but may not be needed if an alternating inspiratory/abdominal muscle stimulation pattern is established.

The invention has now been described in detail. However, it will be appreciated that certain changes and modifications may be made. Therefore, the scope and content of this invention are not limited by the foregoing description. Rather, the scope and content are to be defined by the following claims.

WHAT IS CLAIMED IS:

1. A method for increasing cardiopulmonary circulation when performing cardiopulmonary resuscitation on a patient in cardiac arrest, the method comprising:  
during a decompression phase, stimulating at least some of the respiratory muscles to contract sufficient to cause the patient to gasp and to cause an increase in the magnitude and duration of negative intrathoracic pressure during the decompression phase, thereby enhancing the amount of venous blood flow into the heart and lungs.
2. A method as in claim 1, further comprising actively compressing the patient's chest during a compression phase.
3. A method as in claim 2, further comprising indicating to a rescuer when to apply chest compressions in an alternating fashion with respiratory muscle stimulation.
4. A method as in claim 1, further comprising stimulating the respiratory muscles to contract at a frequency in the range from about 30 to about 120 times per minute.
5. A method as in claim 1, wherein the stimulating step comprises delivering electrical current to the diaphragm or the chest wall muscles.
6. A method as in claim 1, wherein the stimulating step comprises delivering electrical current or electromagnetic energy to the phrenic nerve.
7. A method as in claim 1, further comprising periodically supplying respiratory gases to the patient's lungs to ventilate the patient.
8. A method as in claim 1, further comprising periodically occluding airflow to the lungs during at least a portion of the decompression phase by placing an impedance valve into the patient's airway, wherein the impedance valve is set to open after a predetermined threshold negative intrathoracic pressure is reached or exceeded.
9. A method for increasing cardiopulmonary circulation when performing cardiopulmonary resuscitation on a patient in cardiac arrest, the method comprising:  
periodically stimulating at least some of the abdominal muscles contract sufficient to enhance the amount of venous blood flow into the heart and lungs.

10. A method as in claim 9, further comprising electrically stimulating the abdominal muscles to contract, while preventing respiratory gases from exiting the lungs, and then permitting respiratory gases from exiting the lungs to produce a cough.

11. A method as in claim 9, further comprising actively compressing the patient's chest during a compression phase and permitting the patient's chest to rise during a decompression phase, and further comprising stimulating the abdominal muscles during a time period which ranges between a latter portion of the decompression phase to a mid portion of the compression phase.

12. A method as in claim 11, further comprising periodically occluding airflow to the lungs during at least a portion of the decompression phase by placing an impedance valve into the patient's airway, wherein the impedance valve is set to open after a predetermined threshold negative intrathoracic pressure.

13. A method as in claim 11, further comprising indicating to a rescuer when to apply chest compressions in relation to abdominal stimulation.

14. A method for increasing cardiopulmonary circulation when performing cardiopulmonary resuscitation on a patient in cardiac arrest, the method comprising:

during a compression phase, compressing the patient's chest;

during a decompression phase, stimulating at least some of the respiratory muscles to contract sufficient to cause the patient to gasp and to cause an increase in the magnitude and duration of negative intrathoracic pressure during the decompression phase, thereby enhancing the amount of venous blood flow into the heart and lungs; and

stimulating at least some of the abdominal muscles to contract during a time period which ranges between a latter portion of the decompression phase to a mid portion of the compression phase to enhance the amount of venous blood flow into the heart and lungs.

15. A method as in claim 14, further comprising delivering electrical or magnetically generated current to at least some of the respiratory muscles or nerves.

16. A method as in claim 14, further comprising electrically stimulating the abdominal muscles to contract.

17. A method as in claim 14, further comprising periodically occluding airflow to the lungs during at least a portion of the decompression phase by placing an impedance valve into the patient's airway, wherein the impedance valve is set to open after a predetermined threshold negative intrathoracic pressure has been reached or exceeded.

18. A method for increasing cardiopulmonary circulation when performing cardiopulmonary resuscitation on a patient, the method comprising:  
in an alternating manner, stimulating at least some of the respiratory muscles to contract sufficient to cause the patient to gasp and to cause an increase in the magnitude and duration of negative intrathoracic pressure during the decompression phase, thereby enhancing the amount of venous blood flow into the heart and lungs, and stimulating at least some of the abdominal muscles contract sufficient to enhance the amount of venous blood flow into the heart and lungs.

19. A method as in claim 18, further comprising delivering electrical or magnetically generated current to at least some of the respiratory muscles or nerves.

20. A method as in claim 18, further comprising electrically stimulating the abdominal muscles to contract.

21. A method as in claim 20, further comprising occluding the flow of respiratory gases out of the lungs during at least a portion of the time the abdominal muscles are stimulated to contract.

22. A method as in claim 18, further comprising periodically occluding airflow to the lungs during at least a portion of the decompression phase by placing an impedance valve into the patient's airway, wherein the impedance valve is set to open after a predetermined threshold negative intrathoracic pressure has been reached or exceeded.

23. A method for increasing cardiopulmonary circulation when performing cardiopulmonary resuscitation on a patient, the method comprising:  
stimulating at least some of the abdominal muscles to contract; and  
occluding the patient's airway for a time period in the range from about 10 ms to about 500 ms while stimulating the abdominal muscles.

24. A method as in claim 23, further comprising compressing the patient's chest during a compression phase.

25. A method for increasing cardiopulmonary circulation when performing cardiopulmonary resuscitation on a patient, the method comprising:  
repeatedly field stimulating the chest to cause an increase in intrathoracic pressure followed by a decrease in intrathoracic pressure.

26. A method as in claim 25, wherein the field stimulating step comprises electrically stimulating the thoracic musculature.

27. A method as in claim 25, further comprising stimulating at least some of the abdominal muscles to contract in an alternating fashion with the field stimulation.

28. A device to assist in the performance of a cardiopulmonary resuscitation procedure, the device comprising:  
an endotracheal tube which is adapted to be placed into a patient's airway, the endotracheal tube having at least one electrode which is operable to repeatedly stimulate the respiratory muscles to contract to cause the patient to gasp.

29. A device as in claim 28, further comprising a pressure-responsive valve operably coupled to the endotracheal tube to prevent respiratory gases from entering the patient's lungs until a threshold negative intrathoracic pressure is exceeded.

30. A stimulation system, comprising:  
a plurality of electrodes that are adapted to be placed onto a patient's body at spaced apart locations; and  
a controller coupled to the electrodes, the controller being configured to sequentially actuate at least some of the electrodes to produce a wave of muscle contractions to force venous blood into the patient's thorax and to cause the patient's diaphragm to be pushed upward.

31. A system as in claim 30, further comprising an indicator coupled to the controller to indicate when a rescuer may manually compress the patient's chest.

32. A system as in claim 30, wherein the controller is configured to actuate a second set of electrodes in an alternating manner with the first set to stimulate the patient's respiratory muscles.

33. A system as in claim 32, wherein the controller is configured to actuate the second set of electrodes about mid-way through actuation of the first set.

34. A system as in claim 33, wherein the controller is further configured to sense cardiac electrical activity using the first or second set of electrodes.

35. A system as in claim 34, wherein the controller is further configured to send one or more signals to the first or the second set of electrodes to transthoracically or transtracheally pace the heart and to defibrillate the heart.

36. A system to produce a cough, comprising:  
at least one electrode that is adapted to be positioned on a patient to stimulate the abdominal muscles to contract;  
a valve having an open position and a closed position; and  
a controller coupled to the electrode and the valve, the controller being configured to open the valve while the electrode is actuated to cause the patient to cough.

37. A system as in claim 32, wherein the controller is configured to open the valve for a time in the range from about 10 ms to about 500 ms after the abdominal muscles are stimulated to contract.

38. A stimulation system comprising:  
at least a first electrode that is adapted to be placed onto a patient to stimulate a respiratory muscle;  
at least a second electrode that is adapted to be placed onto the patient to stimulate abdominal contraction; and  
a controller coupled to the first and second electrodes, the controller being configured to alternate actuation of the first and the second electrode to stimulate contraction of the respiratory muscle followed by stimulation of the abdomen.



39. A system as in claim 38, further comprising a valve coupled to the controller, the valve being adapted to regulate the flow of respiratory gases from the patient.

40. A system as in claim 38, further comprising a valve coupled from the controller, the valve being adapted to regulate the flow of respiratory gases to the patient.

41. A system as in claim 38, wherein the controller is further configured to sense cardiac electrical activity using at least one of the electrodes or one or more other electrodes.

42. A system as in claim 41, wherein the controller is further configured to send one or more signals to at least one of the electrodes or one or more other electrodes to transthoracically or transtracheally pace the heart and to defibrillate the heart.

43. A method for increasing cardiopulmonary circulation when performing cardiopulmonary resuscitation which involves a compression phase and a recovery phase, the method comprising:

actively compressing a patient's chest during the compression phase; and stimulating the diaphragm to contract to cause an increase in the magnitude and duration of negative intrathoracic pressure during the recovery phase and to enhance the amount of venous blood flow into the heart and lungs.

44. A method as in claim 43, wherein the stimulating step comprises delivering electrical current to the diaphragm, the abdomen, or the phrenic nerve.

45. A method as in claim 43, further comprising stimulating the diaphragm to contract only during the recovery phase.

46. A method as in claim 43, further comprising periodically supplying respiratory gases to the patient's lungs to ventilate the patient and periodically delivering an electrical impulse to transthoracically pace the heart.

47. A method as in claim 43, further comprising periodically occluding airflow to the lungs during at least a portion of the recovery phase by placing an impedance valve into the patient's airway, wherein the impedance valve is set to open after a predetermined threshold negative intrathoracic pressure.

48. A method as in claim 43, further comprising sensing when the patient's chest is actively compressed and stimulating the diaphragm to contract after sensing the chest compression.

49. A method as in claim 43, wherein the compression phase and the recovery phase are cyclically repeated, and wherein the diaphragm is stimulated to contract only during certain segments of the cycles.

50. A method as in claim 43, further comprising periodically delivering a defibrillation shock.

51. A device to assist in the performance of a cardio pulmonary resuscitation procedure, the device comprising:

a compression member which is adapted to be placed in the proximity of the sternum and to be operated to compress the chest, the compression member including a sensor to determine when the patient's chest has been compressed; and

at least one electrode coupled to the sensor to deliver electrical current to the diaphragm to cause the diaphragm to contract, wherein the electrode delivers the electrical current to the diaphragm based on information from the sensor regarding the state of chest compression to stimulate the diaphragm to contract to cause an increase in the magnitude and duration of negative intrathoracic pressure during a recovery phase and to enhance the amount of venous blood flow into the heart and lungs.

52. A device as in claim 51, further comprising a pair of arms extending from the compression member, wherein the electrode is coupled to one of the arms and another electrode is coupled to the other arm.

53. A device as in claim 52, wherein the arms are fashioned so as to be adapted to be received over a lower portion of the rib cage when the compression member is over the sternum.
54. A device as in claim 52, wherein the arms are constructed of a flexible material.
55. A device as in claim 51, further comprising a voltage controller to manually control the voltage at the electrode.
56. A device as in claim 55, further comprising an actuator coupled to the sensor, the actuator actuating the electrode when an appropriate number of compressions have been sensed.
57. A device as in claim 51, further comprising a metronome to assist a rescuer in performing regular chest compressions with the compression member.
58. A device as in claim 51, further comprising a power source coupled to the electrode.
59. A device as in claim 51, wherein the electrode comprises an adhesive electrically conductive pad.
60. A device as in claim 51, wherein the electrode is adapted to be coupled to a defibrillator.
61. A device as in claim 51, wherein the electrode is adapted to be coupled to a pacer to stimulate the heart.
62. A device to assist in the performance of a cardio pulmonary resuscitation procedure, the device comprising:  
a mechanical compression device comprising a compression member which is operable to compress the chest and a sensor to determine when a compressive force is applied to the chest by the compression member; and

at least one electrode electrically coupled to the sensor to deliver electrical current to the diaphragm to cause the diaphragm to contract, wherein the electrode delivers the electrical current to the diaphragm based on information from the sensor regarding the state of compression of the chest produced by the compression member to stimulate the diaphragm to contract to cause an increase in the magnitude and duration of negative intrathoracic pressure during a recovery phase and to enhance the amount of venous blood flow into the heart and lungs.

63. A kit to assist in the performance of a cardio pulmonary resuscitation procedure, the kit comprising:

- a compression member;
- a sensor to detect chest compression;
- at least one electrode coupled to the sensor; and
- instructions describing placement of the compression member and the electrode on a patient, describing a manner for compressing a patient's chest with the compression member, and describing stimulation of the diaphragm with the electrode to cause the diaphragm to contract to cause an increase in the magnitude and duration of negative intrathoracic pressure during the recovery phase to enhance the amount of venous blood flow into the heart and lungs.

64. A method for increasing cardiopulmonary circulation when performing cardio pulmonary resuscitation which involves a compression phase and a recovery phase, the method comprising:

- actively compressing a patient's chest during the compression phase;
- sensing compression of the patient's chest; and
- stimulating the diaphragm to contract after sensing the chest compression to cause an increase in the magnitude and duration of negative intrathoracic pressure during the recovery phase to enhance the amount of venous blood flow into the heart and lungs.

65. A method as in claim 64, further comprising sensing when the patient's chest is compressed and stimulating the diaphragm to contract after sensing a chest compression.

66. A method for increasing cardiopulmonary circulation when performing cardio pulmonary resuscitation which involves a compression phase and a decompression phase, the method comprising:

actively compressing a patient's chest during the compression phase; and stimulating at least some of the respiratory muscles to contract to cause an increase in the magnitude and duration of negative intrathoracic pressure during the decompression phase, thereby enhancing the amount of venous blood flow into the heart and lungs.

67. A method as in claim 66, further comprising stimulating the respiratory muscles to contract at a frequency in the range from about 30 to about 120 times per minute.

68. A method as in claim 66, wherein the stimulating step comprises delivering electrical current to the diaphragm or the chest wall muscles.

69. A method as in claim 66, wherein the stimulating step comprises delivering electrical current or magnetic energy to the phrenic nerve.

70. A method as in claim 66, further comprising stimulating the respiratory muscles to contract only during the decompression phase.

71. A method as in claim 66, further comprising periodically supplying respiratory gases to the patient's lungs to ventilate the patient.

72. A method as in claim 66, further comprising sensing when the patient's chest is actively compressed and stimulating the respiratory muscles to contract after sensing the chest compression and further comprising periodically occluding airflow to the lungs during at least a portion of the decompression phase by placing an impedance valve into the patient's airway, wherein the impedance valve is set to open after a predetermined threshold negative intrathoracic pressure.

73. A method as in claim 66, further comprising sensing when the patient's chest is actively compressed and stimulating the respiratory muscles to contract after sensing the chest compression.

74. A device to assist in the performance of a cardio pulmonary resuscitation procedure, the device comprising:

a compression member which is adapted to be placed in the proximity of the sternum and to be operated to compress the chest, the compression member including a sensor to determine when the patient's chest has been compressed; and

at least one electrode coupled to the sensor to deliver electrical current to at least some of the respiratory muscles to cause the stimulated respiratory muscles to contract, wherein the electrode delivers the electrical current to the respiratory muscles based on information from the sensor regarding the state of chest compression.

75. A device as in claim 74, further comprising a pair of arms extending from the compression member, and at least one electrode coupled to an end of each arm.

76. A device as in claim 75, wherein the arms are fashioned so as to be adapted to be received over a lower portion of the rib cage when the compression member is over the sternum.

77. A device as in claim 75, further comprising an actuator coupled to the compression sensor, the actuator actuating the electrode when an appropriate number of compressions have been sensed.

78. A method for increasing cardiopulmonary circulation when performing cardio pulmonary resuscitation which involves a compression phase and a decompression phase, the method comprising:

actively compressing a patient's chest during the compression phase;

sensing compression of the patient's chest; and

stimulating at least some of the respiratory muscles to contract after sensing the chest compression to cause an increase in the magnitude and duration of negative intrathoracic pressure during the decompression phase, thereby enhancing the amount of venous blood flow into the heart and lungs.

79. A method as in claim 78, further comprising stimulating the respiratory muscles to contract at a frequency in the range from about 30 to about 120 times per minute.

80. A method as in claim 78, wherein the stimulating step comprises delivering electrical current to the diaphragm and/or the chest wall muscles.

81. A method as in claim 78, wherein the stimulating step comprises delivering electrical current or magnetic energy to the phrenic nerve.

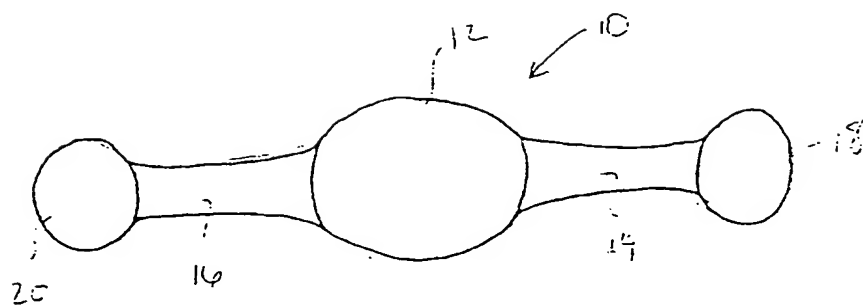


FIG. 1

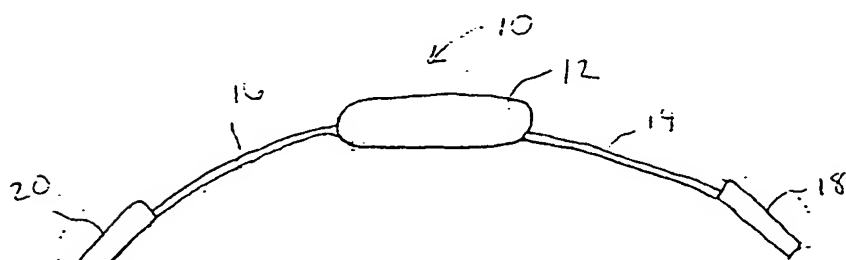


FIG. 2

FIG. 3

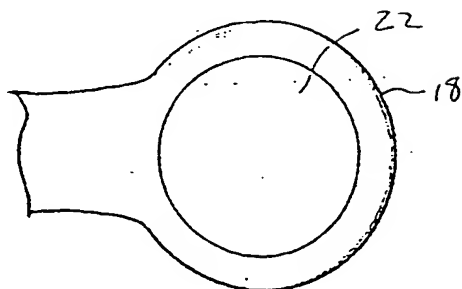
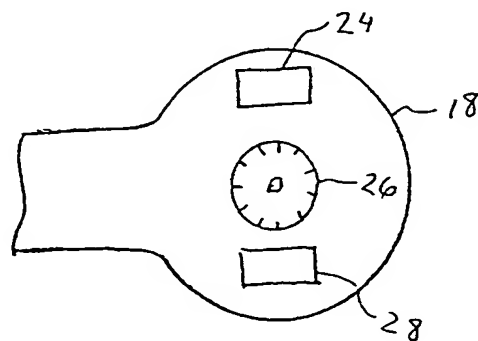


FIG. 4





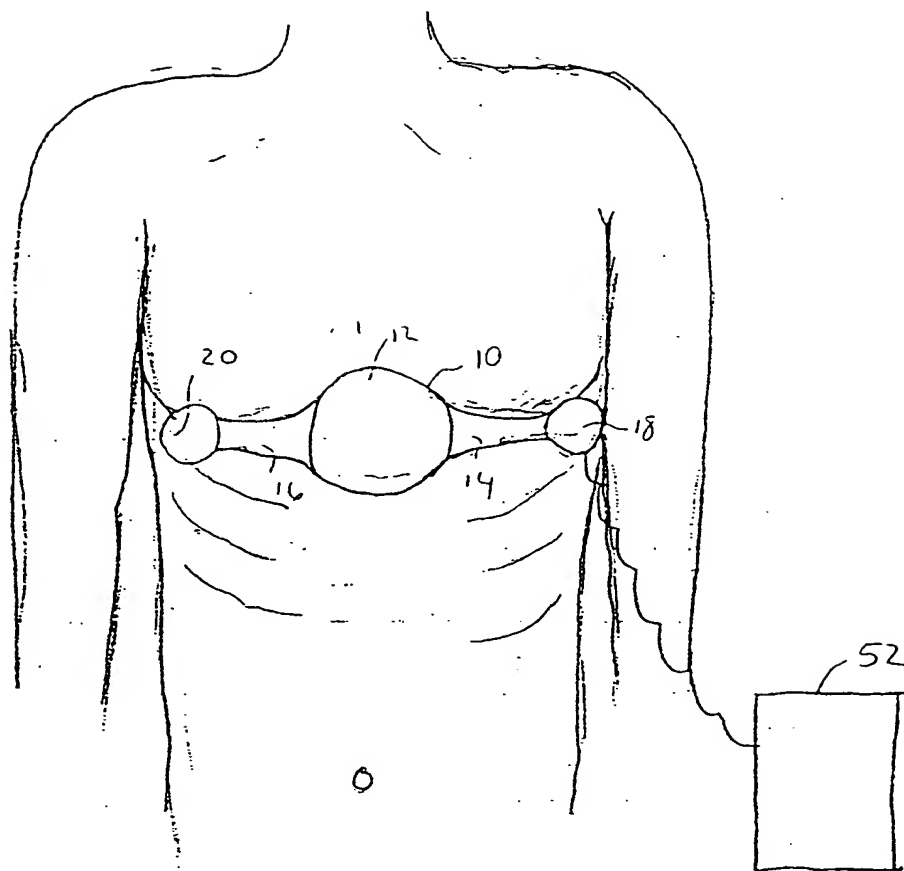


FIG. 7

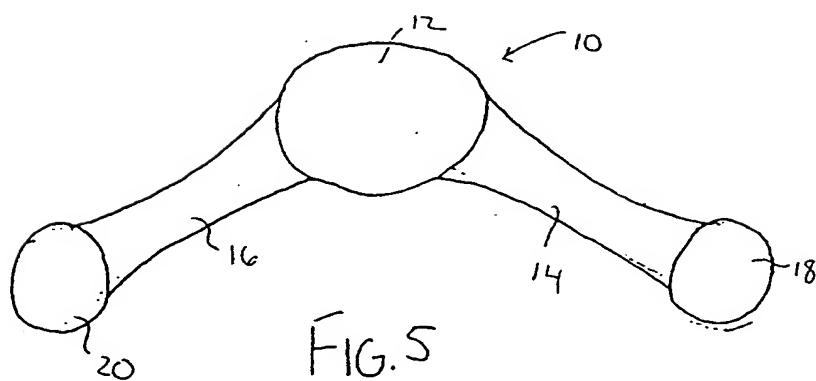


FIG. 5

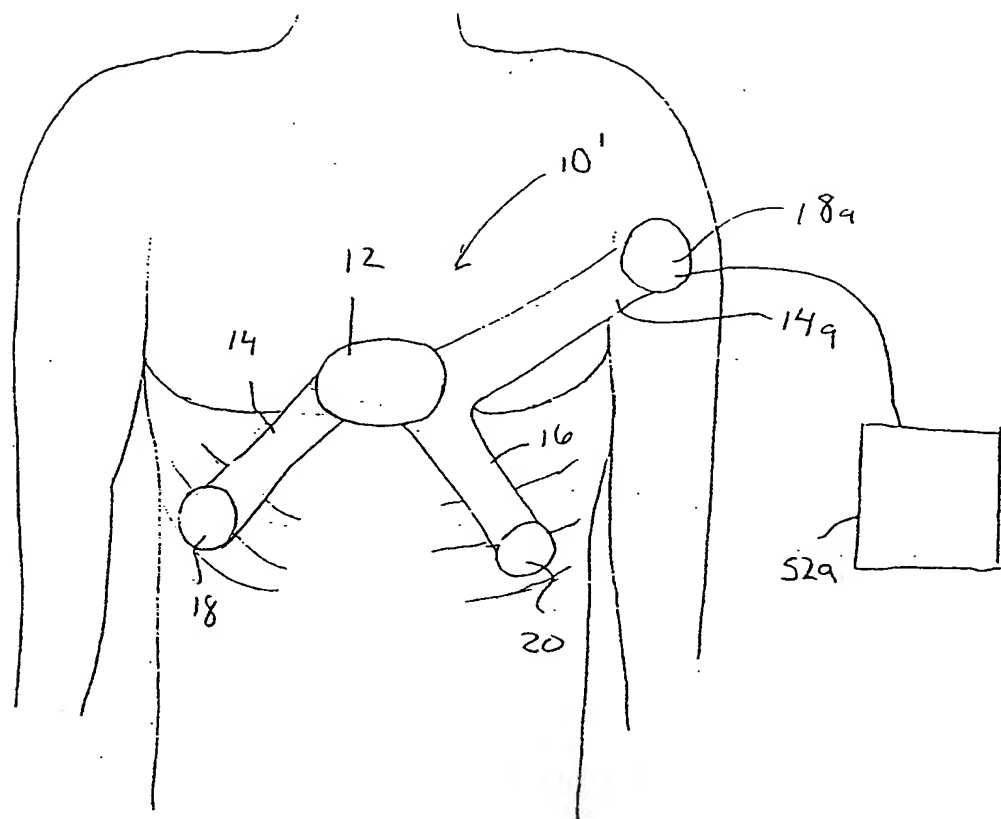


FIG. 5A

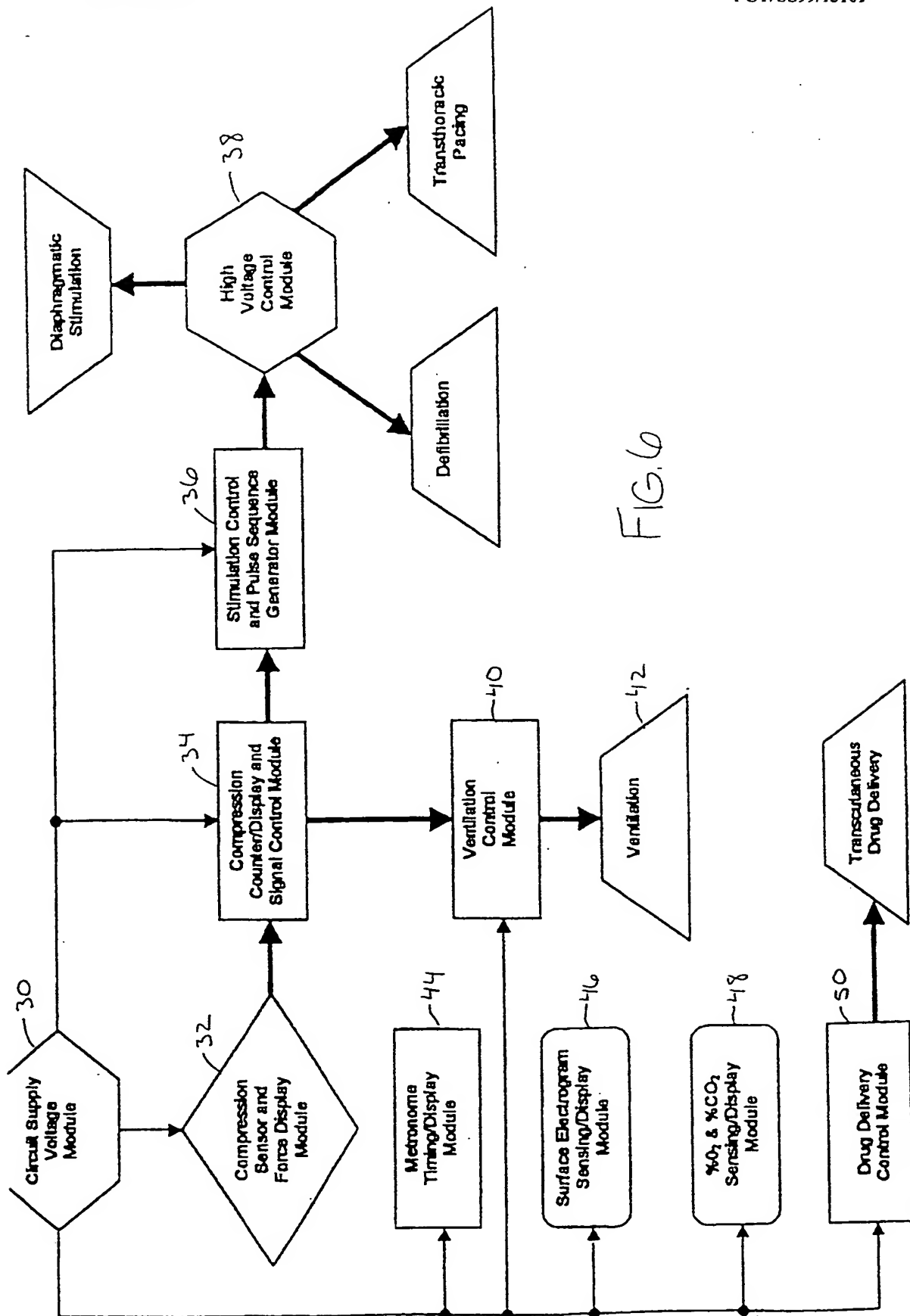


FIG. 6

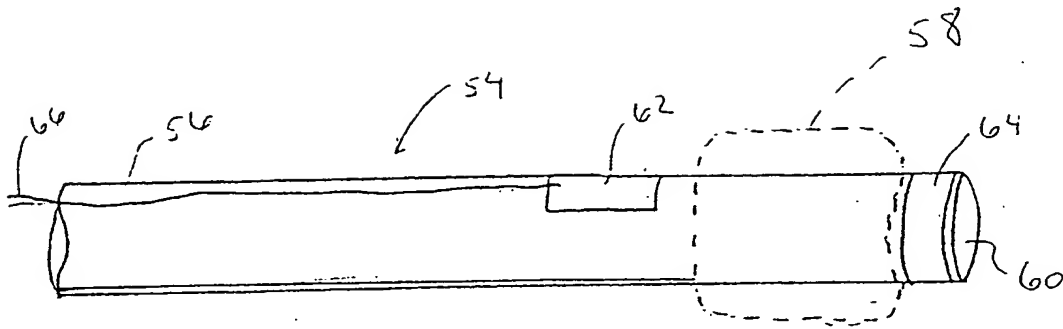


FIG. 8

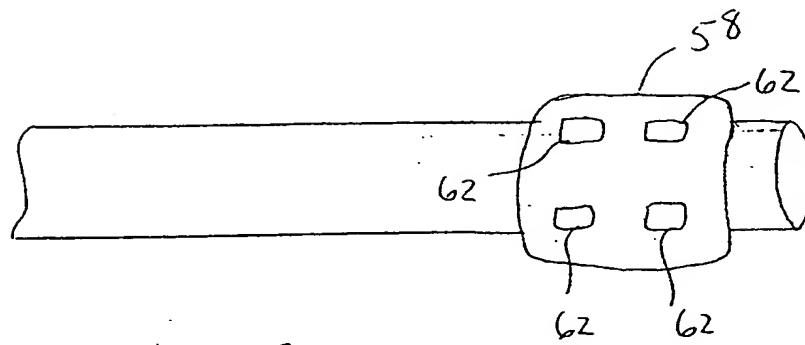


FIG. 8B

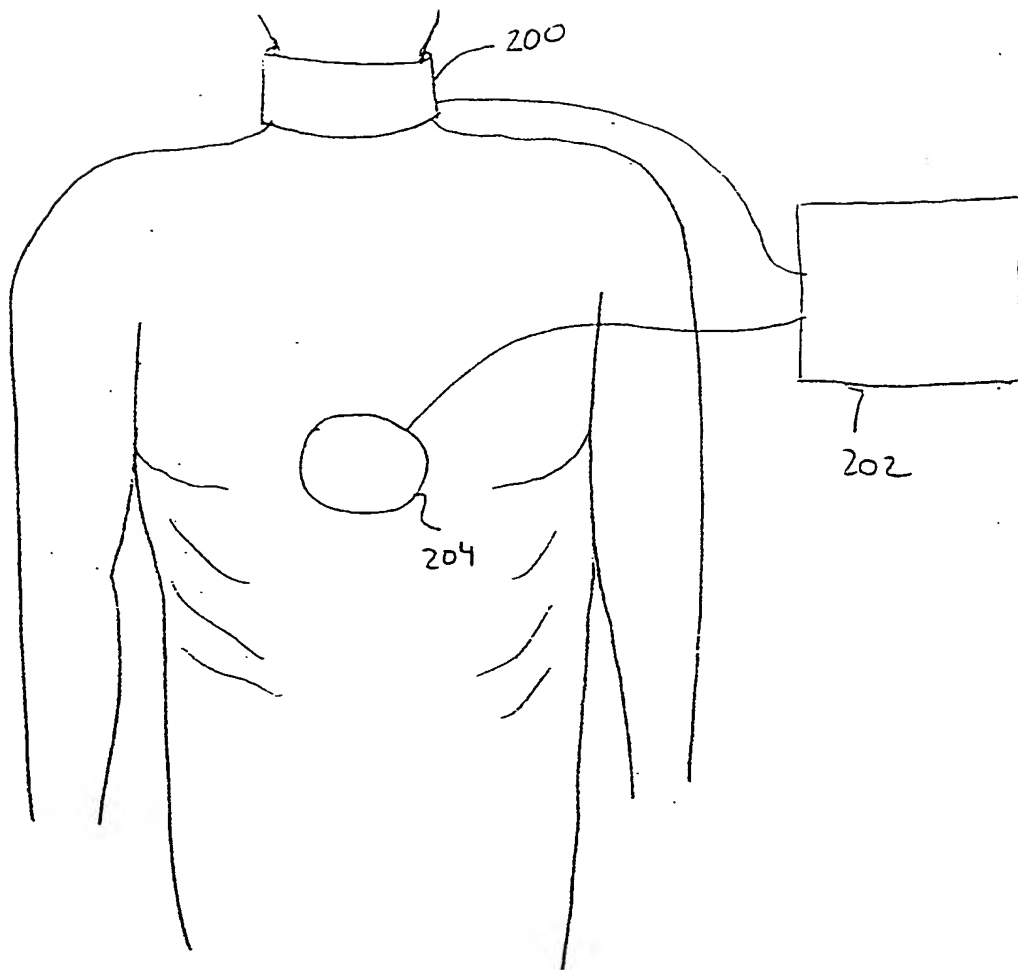


FIG. 8A

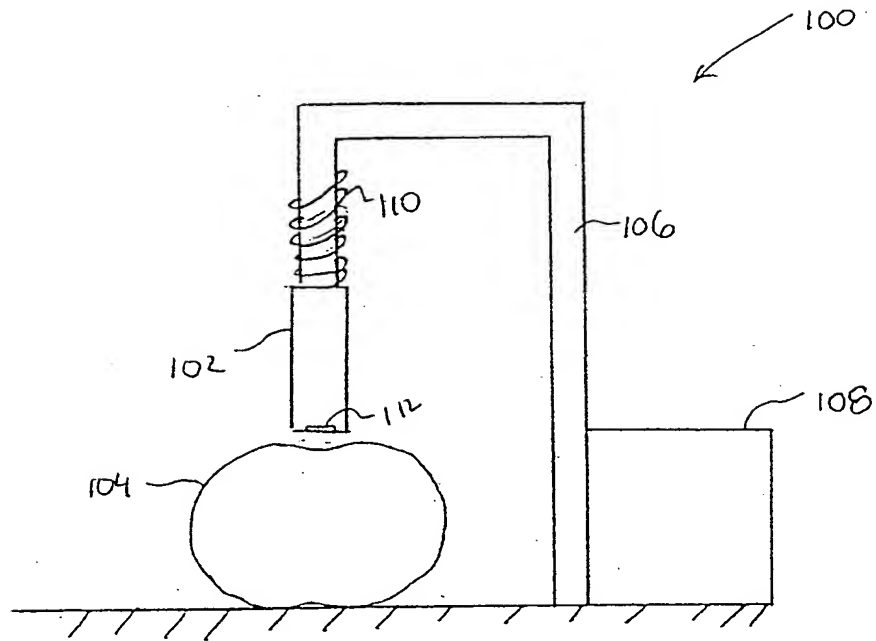


FIG. 9.

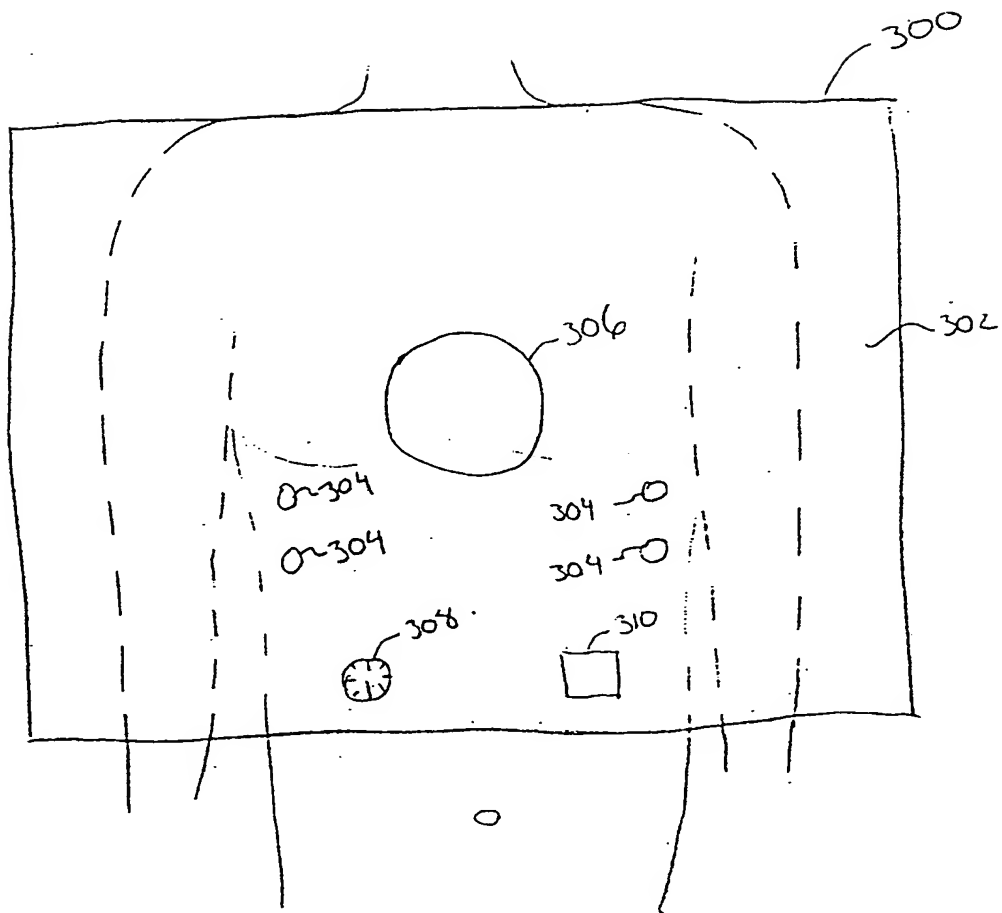


FIG. 10

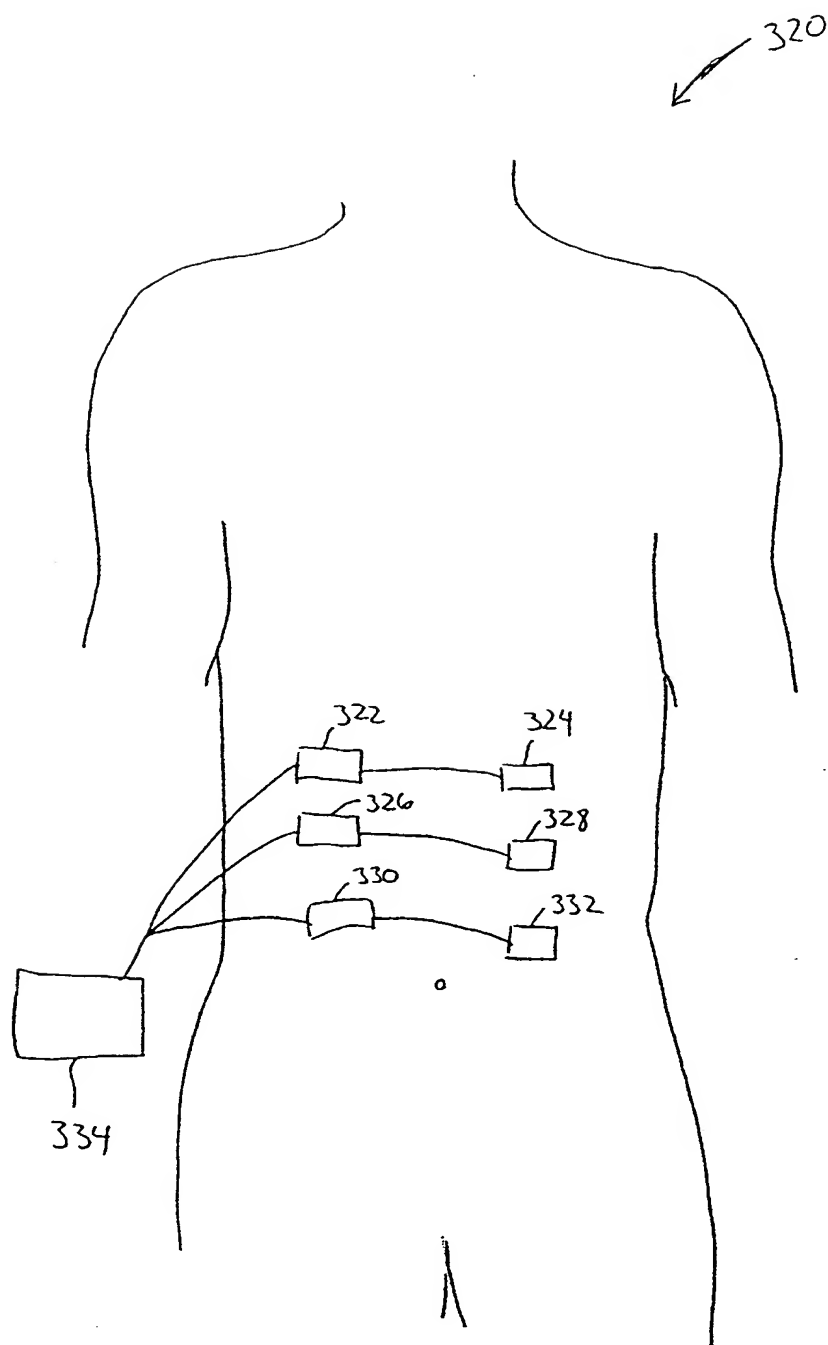


FIG. 11



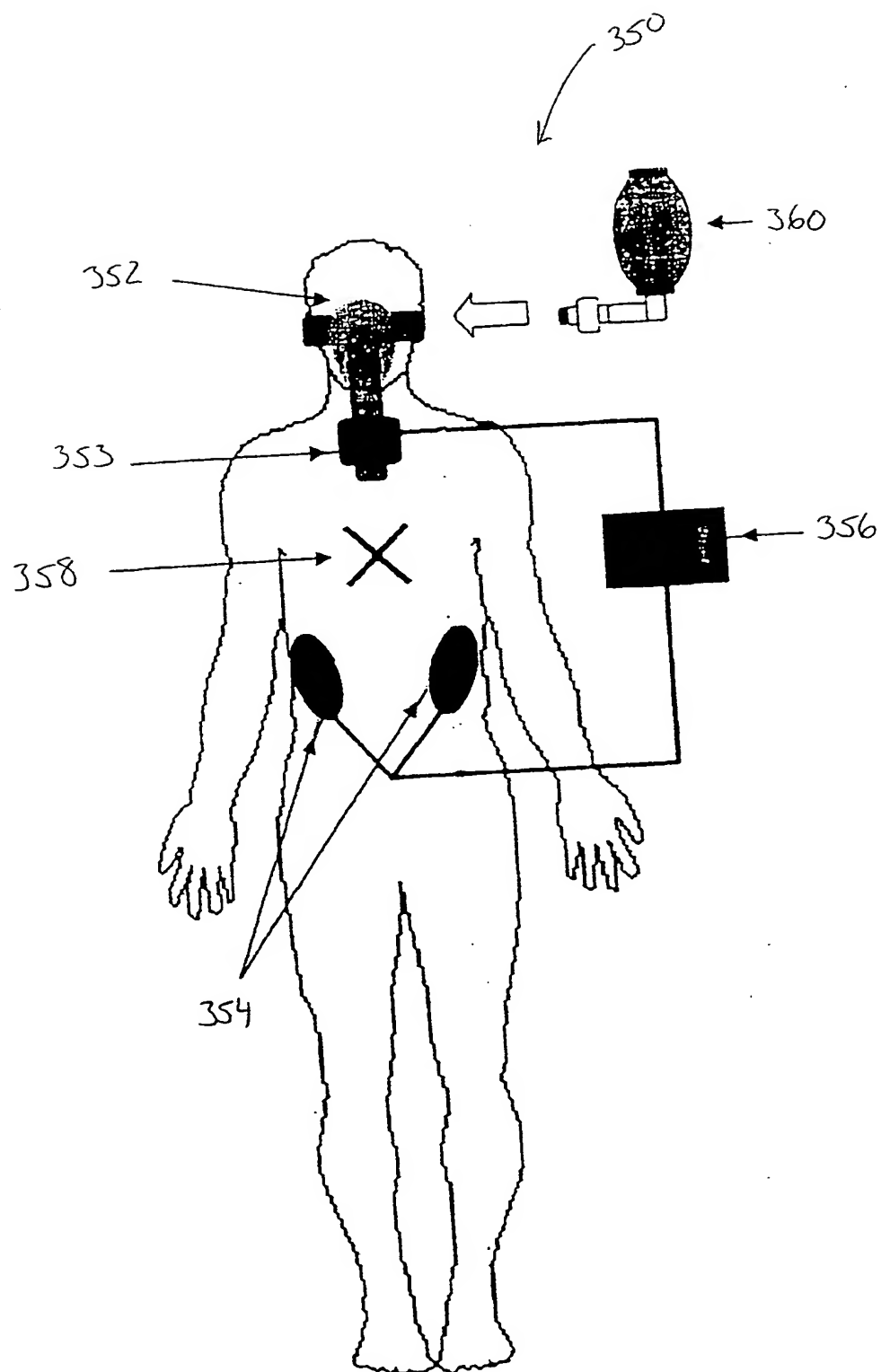


FIG. 12

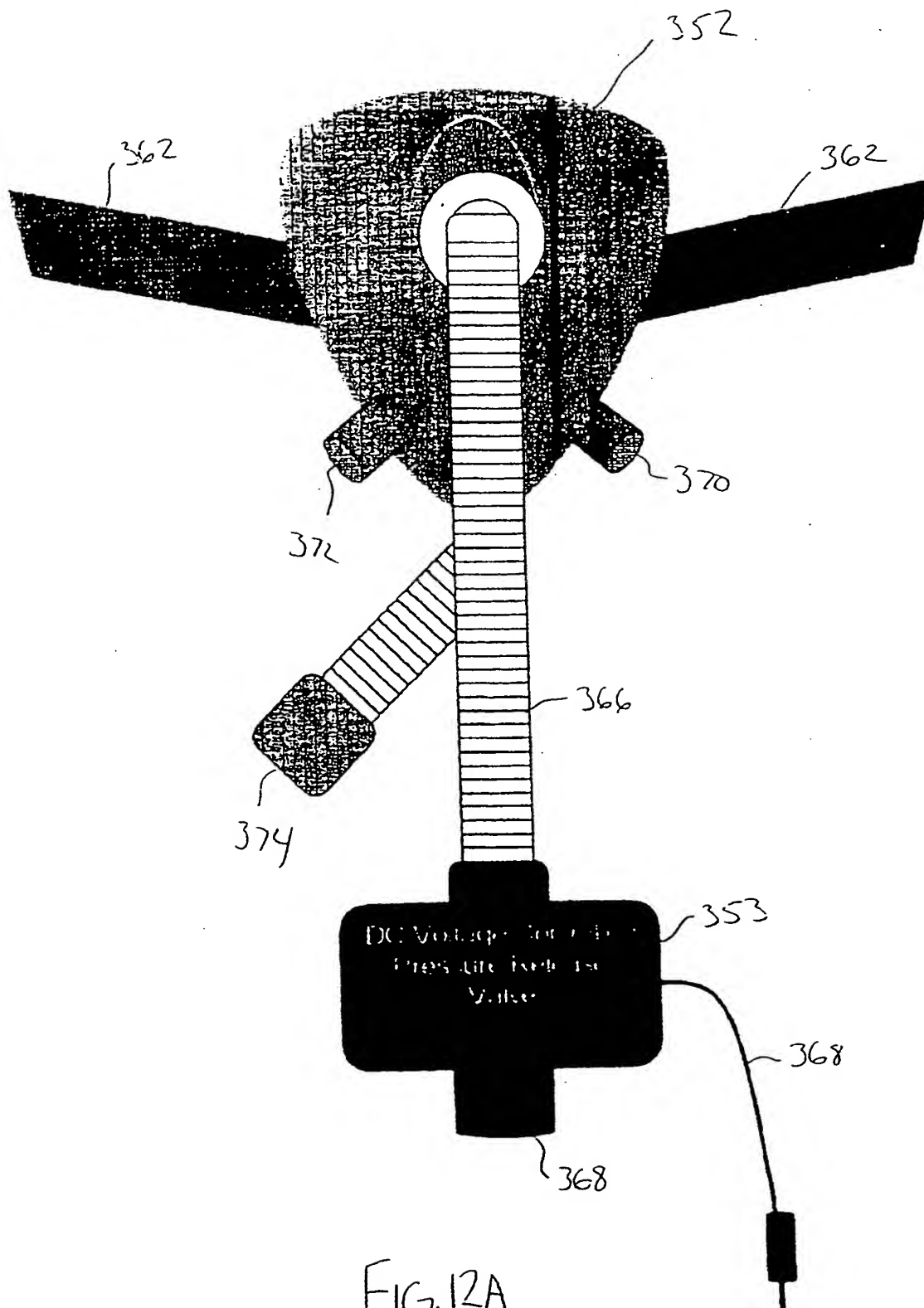


FIG. 12A

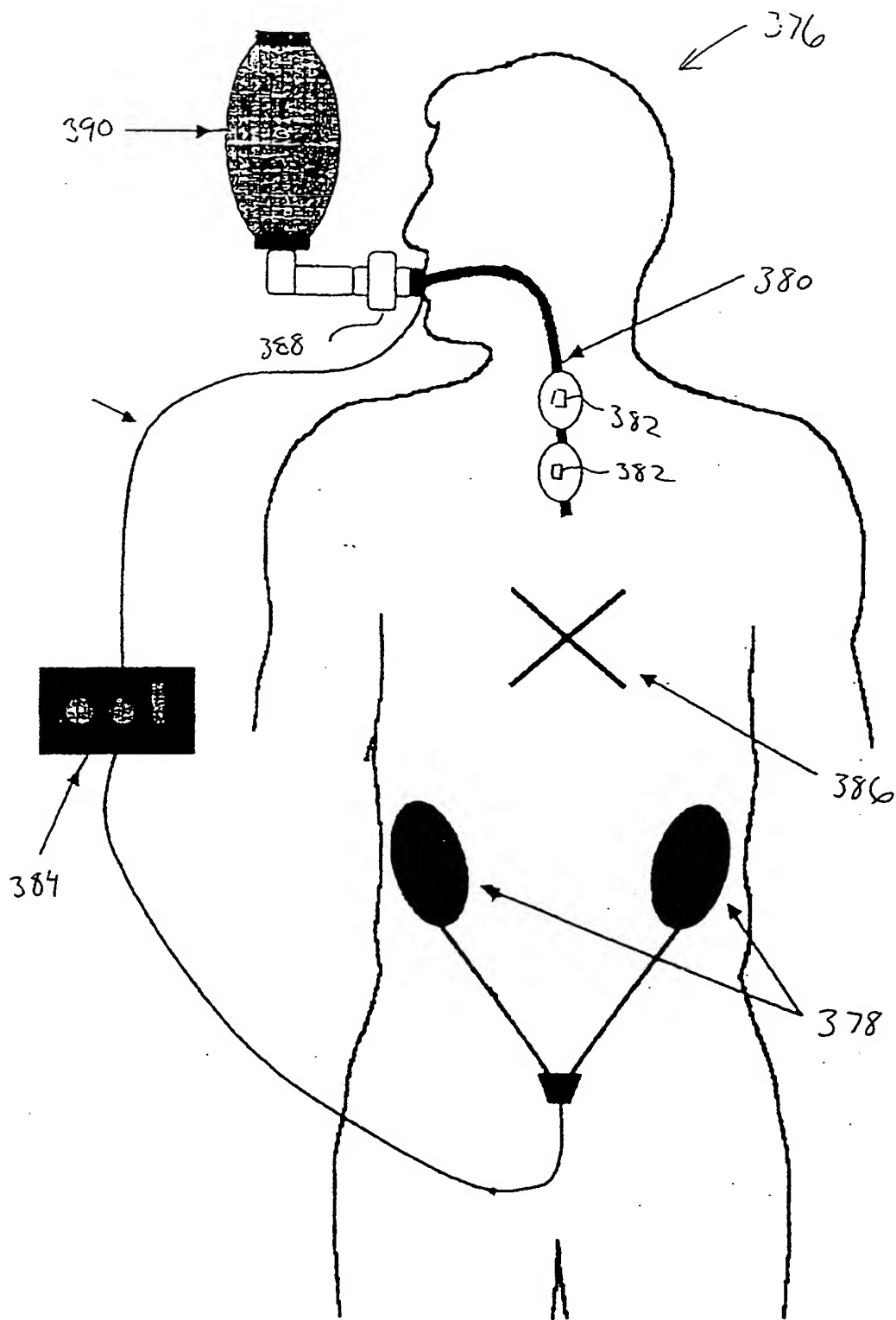


FIG. 12B

**This Page is Inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record**

**BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☒ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☒ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: \_\_\_\_\_

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.**